CHAPTER 23
SECTION 4

DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) DEMONSTRATION PROJECT

1.0. PURPOSE

This demonstration project will compare traditional and cognitive rehabilitation for patients with Traumatic Brain Injury (TBI) under DVHIP Protocol II TBI Rehabilitation: A Controlled Randomized Multicenter Study of Two Interdisciplinary Programs with Adjuvant Pharmacotherapy (DVHIP Protocol II).

2.0. BACKGROUND

2.1. The Conference Report on the Defense Appropriations Act for Fiscal Year 1992 (House Report 102-328) supported the Department of Defense (DoD) to start an initiative for DoD victims of head injuries. The DVHIP was established in February 1992, and funded in part by direct appropriations to DoD(HA) from Congress. The DVHIP represents a unique collaboration among the Department of Defense (DoD), Department of Veterans Affairs (DVA), and the Brain Injury Association. The DVHIP can currently provide services at its DVA facilities only for those patients who are eligible for care within the DVA system. At present, this excludes the majority of TRICARE patients from participation in the DVHIP.

2.2. The current state of the medical literature does not allow for a TRICARE benefit for cognitive rehabilitation as it is considered investigational. The DVHIP has proposed a randomized, prospective trial that would hasten the answers to the current questions of outcomes regarding cognitive rehabilitation. Participation in these clinical trials will improve access to cognitive rehabilitation for TRICARE-eligible beneficiaries when their conditions meet protocol eligibility criteria. DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of cognitive rehabilitation in the treatment of TBI.

2.3. There are four Veterans Affairs Medical Centers (VAMCs) participating in this Demonstration - VAMC Palo Alto, California (known as VA Palo Alto Health Care System (VAPAHCS)); VAMC Minneapolis, Minnesota; VAMC Richmond, Virginia; and, VAMC Tampa, Florida.

2.4. Among TRICARE beneficiaries of all ages (5.4 million), approximately 5,000 have head injuries each year with 1,300 to 1,400 requiring hospitalization. The design of the cognitive rehabilitation protocol is limited to patients between the ages of 17 - 55 years. TRICARE population projections for fiscal year (FY) 1996 include approximately 2.1 million beneficiaries between 17 and 55 years of age. This Demonstration Project is projected to have approximately 100 TRICARE patients with TBI participating in the protocol each year.

2.5. DoD financing of these procedures will assist in meeting clinical trial goals and arrival at conclusions regarding the safety and efficacy of cognitive rehabilitation in the treatment of TBI.

3.0. POLICY

3.1. Effective August 1, 1997, inpatient services for TBI under the DVHIP Protocol II, are authorized for those TRICARE-eligible patients who are:

- Evaluated at one of the four participating VAMCs for acceptance into the DVHIP Protocol II; and/or
- Randomized into a group under the DVHIP Protocol II.

3.2. The actual services will be provided by one of the four participating VAMCs identified in paragraph 2.3., above. Reimbursement to participating VAMCs will be made based on a per diem rate of $600.00 as provided in the memorandum of understanding (MOU) (Figure 23-4-1 through Figure 23-4-4) executed between DoD and each VAMC. The per diem is to cover all professional and institutional charges as specified in the MOU.

3.3. Beneficiary cost-shares applicable under TRICARE shall apply under the Demonstration. No deductible shall apply for inpatient services provided to TRICARE-eligible patients under the Demonstration.

3.4. For individuals with dual VA and DoD eligibility, the VA will be responsible for ensuring that an individual veteran's non-discretionary VA benefits are exhausted before utilizing benefits under the Demonstration. With regard to individuals with VA and DoD eligibility, VA will be responsible for the following beneficiary care: (a) all care for mandatory/non-discretionary veterans, and (b) all care for veterans for service-connected conditions.

3.5. The participating VAMC will be responsible for obtaining information regarding possible third party liability and other health insurance (OHI) coverage of the TRICARE-eligible patient. VAMC will collect from the third party or OHI in accordance with VA procedures and bill any remaining balance of the total per diem amount to the appropriate regional contractor, referencing the Defense and Veterans Head Injury Program Demonstration. In the event that the VAMC is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill will be presented by the participating VAMC to the regional contractor. See paragraph 7.2.

3.6. The Demonstration will terminate upon completion of the DVHIP Protocol II study which is projected to last for three years. However, TRICARE Management Activity (TMA) reserves the right to terminate the claims processing contract for the Demonstration by giving 60 days notice to the contractor.

4.0. APPLICABILITY

4.1. The Demonstration is limited to TRICARE eligibles between the ages of 17 and 55 years of age (on the date of entry into the demonstration) who meet the criteria in the DVHIP

Protocol II (see Figure 23-4-5). The demonstration does not apply to those beneficiaries enrolled in the Continued Health Care Benefit Program.

4.2. The DoD Demonstration project is separate from and not a part of the TRICARE program. Because demonstration benefits are not the same as TRICARE benefits, all inquiries related to the DVHIP protocol must be submitted to the Director, DVHIP (see Figure 23-4-1 through Figure 23-4-4); and, all inquiries related to participation in the Demonstration must be submitted to the Point of Contact (POC) at the participating VAMC (see Figure 23-4-1 through Figure 23-4-4). Claims inquiries and claims related to the Demonstration must be submitted to the appropriate regional contractor referencing the Defense and Veterans Head Injury Program Demonstration.

4.3. Since TRICARE has no authority regarding the DVHIP protocol eligibility criteria, if a patient does not meet the criteria for participation, TRICARE appeal rights do not apply.

4.4. Services to TRICARE beneficiaries not covered under the Demonstration shall be subject to the requirements of the TRICARE program.

5.0. GENERAL DESCRIPTION OF ADMINISTRATIVE PROCESS

5.1. The regional contractor shall verify the TRICARE eligibility of the patient on the Defense Enrollment Eligibility System (DEERS). See paragraph 10.0.

5.2. Patient selection will be made by the DVHIP or the participating VAMC in accordance with the protocol (Figure 23-4-5). The contractor will not be involved in medical necessity or clinical review of the Demonstration claims.

5.3. Claims for approved care under the Demonstration will be submitted to the appropriate regional contractor for processing. See paragraph 10.0. and 11.0.

6.0. ASD(HA) RESPONSIBILITIES

ASD(HA) is the designated Executive Agent for the Demonstration project. They shall designate a project officer in the Office of the DASD (Clinical Services) for the Demonstration. The project officer shall:

- Provide clinical oversight.
- Resolve any clinical issue among DoD, DVHIP and the VA.

7.0. PARTICIPATING VAMC RESPONSIBILITIES

7.1. For individuals with dual VA and TRICARE eligibility, the participating VAMC will be responsible for ensuring that individual veteran's non-discretionary VA benefits are exhausted before utilizing the demonstration benefits (see Figure 23-4-1 through Figure 23-4-4).

7.2. Participating VAMC will be responsible for obtaining information regarding possible third party liability and other health insurance (OHI) coverage of the TRICARE beneficiary.

7.2.1. The VAMC shall collect from third party or the OHI in accordance with VA procedures and bill any remaining balance of the total per diem amount to the appropriate regional contractor within 30 days of the receipt of the payment from the OHI. The VAMC shall ensure proper entry regarding the OHI on the UB-92 claim form before submitting the claim form to the contractor.

7.2.2. In the event that the VAMC is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill shall be presented by the VAMC to the DoD contractor.

7.3. The VAMC shall determine patient acceptance for participation in the Demonstration in accordance with the protocol outlined in Figure 23-4-5.

7.4. Participating VAMC shall request reimbursement for inpatient services provided under the Demonstration completing a UB-92 and submitting the form to the appropriate regional contractor. Reimbursement will be requested based on the negotiated per diem rate of $600 which will cover all professional and institutional services. The VAMC shall be responsible for collecting the beneficiary cost-shares from TRICARE patients. The billing itemization requirements are waived for the participating VAMCs.

7.5. For a TRICARE eligible patient, the VAMC shall submit to the contractor one claim for billing for the initial inpatient evaluation, rehabilitation care, and the initial post-discharge evaluation within 30 calendar days upon completion of the initial post-discharge evaluation. Claims for admission at 6-, 12-, and 24-month follow-ups shall be submitted to the contractor by VAMC within 30 days of completion of each follow-up evaluation. In a case where care of a TRICARE-eligible patient is terminated during or after the initial inpatient evaluation or prior to completion of the treatment under the DVHIP Protocol II, the VAMC shall submit the claims to the contractor within 30 days of such termination.

7.6. The VAMC shall establish a POC to respond to inquiries related to participation in the Demonstration and for coordination with the regional contractors. Unless otherwise agreed between the VAMC and TMA, the coordination support by the VAMC shall be provided for up to 12 months after termination of the demonstration.

7.7. VAMC shall appoint a social worker/case manager to assist the TRICARE beneficiaries in placement following discharge to ensure they receive the full benefit of any available health care entitlements.

8.0. DVHIP RESPONSIBILITIES

- Respond to inquiries related to the DVHIP Protocol.
- Provide status updates to ASD(HA).

9.0. TMA RESPONSIBILITIES

TMA will provide for:

- Demonstration claims processing via specific contractual arrangement with one or more contractors.

- Periodic review and evaluation of the Demonstration claims processing.
- Specific written guidance to the contractor(s) regarding claims processing under the terms of the Demonstration.
- Public affairs functions to properly inform and periodically update the patient and provider communities regarding the terms of the Demonstration.

10.0. CONTRACTOR RESPONSIBILITIES

The contractor shall:

10.1. Verify the patient's eligibility on the Defense Enrollment Eligibility letter as appropriate (see Figure 23-4-6).

10.1.1. If the DEERS reflects that the patient is not eligible, a notice shall be sent by the contractor to the patient/sponsor that in order for Demonstration benefits to be paid, the patient must be listed as eligible on DEERS. The patient shall be referred to the pass/ID card section of the military installation nearest to their home for an eligibility determination.

10.1.2. If a patient is listed on DEERS as being eligible as of the date of entry into the Demonstration, all services provided by the participating VAMC during the course of Demonstration will be covered.

10.2. Publish a toll free telephone number to receive inquires related to the demonstration and claims. The phone must be staffed 7 hours a day during normal business hours.

10.3. Publish a mailing address to which Demonstration inquiries and claims may be sent for response and/or claims processing.

10.4. Refer eligible patients for evaluation to the participating VAMC that is nearest to the patient's residence.

10.5. Refer any inquiries regarding beneficiary participation in the Demonstration to the POC at the participating VAMC. (See Figure 23-4-1 through Figure 23-4-4.)

10.6. Refer any inquiries regarding the DVHIP protocol to the Director, DVHIP. (See Figure 23-4-1 for the address and phone number of the Director, DVHIP.)

10.7. Establish and maintain a database of patients participating in the Demonstration. The database shall include the patient's name, sponsor, social security number, facility name and address and total cost.

10.8. Provide the name, address, and phone number of the Demonstration point of contact to the participating VAMCs to assist in resolving claims, billings and DEERS eligibility verification related issues.

11.0. CLAIMS PROCESSING REQUIREMENTS

11.1. The contractor shall follow the provisions of the respective MOUs (Figure 23-4-1 through Figure 23-4-4).

11.2. The contractor shall verify TRICARE eligibility on the DEERS upon request from participating VAMCs or sponsors and/or prior to payment.

11.3. Inpatient (professional and institutional) services provided as part of the DVHIP Protocol II will be reimbursed based on a per diem rate of $600. The participating VAMC must submit the claim to the contractor on a UB-92.

11.4. Claims are to be submitted to the appropriate regional contractor by the VAMC in accordance with the instructions found in paragraph 7.2. and 7.5.

11.5. Cost-shares applicable to TRICARE shall also apply under this Demonstration. No deductibles shall apply.

11.5.1. The contractor shall query the Central Deductible and Catastrophic Cap File (CDCF) to determine the status of catastrophic cap met amounts for TRICARE eligible beneficiaries at the time the costs are listed on the voucher for processing and payment.

11.5.2. The contractor shall determine what expenses to apply to the catastrophic cap and reports these to the CDCF. These expenses shall be reported at the same time the costs are listed on the voucher for processing, prior to payment of the claim.

11.5.3. The contractor shall use query type 80. Type 80 (nonclaim update) is used to request crediting of amounts since this is a manual process.

11.6. Third party liability and double coverage provisions apply and determination of such is the responsibility of the participating VAMC. See paragraph 7.2.

11.7. In double coverage situations, the Demonstration will pay the balance after the other health insurance payment has been applied by participating VAMC. See paragraph 7.2.

11.8. The contractor shall ensure that the amount billed by the VAMC is correctly calculated based on the per diem rate of $600 and application of any OHI and process the claim.

11.9. The contractor and the participating VAMC shall attempt to resolve any billing/claim issue. If an issue remains unresolved for 30 days, it shall be brought to the attention of TMA, Managed Care Support Office, 16401 East Centretech Parkway, Aurora, CO 80011-9066.

11.10. Claims for services provided under the Demonstration project will be processed manually.

11.11. A Nonavailability Statement (NAS) is not required under the Demonstration.

11.12. The contractor will make payments (from their letter of credit account(s) to each participating VAMC as required under this Demonstration. A separate letter of credit is not required.

11.12.1. A voucher will be submitted as needed (but no more than once monthly) to TMA, Contract Resource Management, 16401 East Centretech Parkway, Aurora, CO 80011-9066, by express mail. The voucher will include a summary of payments being made and copies of the supporting documents for the payments. The summary of payments should be subtotaled by uniformed service involved and should include who payment was made to and amounts being paid. Voucher number will be in the same format as DRG pass-through vouchers except the last two digits will be service involved starting with a "5" (Army "51", Air Force "52", Navy "53", Other "55").

11.12.2. Checks will not be released until clearance is received from TMA, Contract Resource Management, Clearance may be made telephonically but will be confirmed by fax.

11.13. Once processing is complete, the hard copy claims and any supporting documentation shall be filed alphabetically by the beneficiary last name by year. The claims shall be maintained on-site until the Demonstration is complete. Once the Demonstration is complete, claims and supporting documentation will be transferred to the Federal Records Center and shall be retained for an additional six years.

11.14. Unless otherwise directed, the contractor shall provide for the claims processing support for the Demonstration for up to 12 months after termination of the demonstration.

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE DEPARTMENT OF VETERANS AFFAIRS PALO ALTO HEALTH CARE SYSTEM
PALO ALTO, CALIFORNIA
AND
THE DEPARTMENT OF DEFENSE

SUBJECT: Care of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE Beneficiaries in the Veterans Affairs Palo Alto Health Care System (VAPAHCS), Palo Alto, California, under the Defense and Veterans Head Injury Program Protocol II.

I. PURPOSE

This Memorandum of Understanding (MOU) is to establish guidance for inpatient care for TRICARE/CHAMPUS beneficiaries in the VAPAHCS, Palo Alto, California (hereinafter referred to as "VAPAHCS"), under a demonstration project in which the Department of Defense (DoD) will participate in the DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) PROTOCOL II TRAUMATIC BRAIN INJURY (TBI) REHABILITATION: A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARAMACOTHERAPY.

II. AUTHORITY

This MOU is authorized by Section 201 of the Veterans Health Care Act of 1992, Pub. L. 102-585, 38 U.S.C. 8111, and 10 U.S.C. 1104.

III. POLICY

1. Effective August 1, 1997, the VAPAHCS shall provide inpatient services for TBI for the TRICARE/CHAMPUS-eligible patients according to the DVHIP Protocol II dated December 23, 1994 (attached).

2. The DoD shall reimburse VAPAHCS based on a negotiated per diem rate of $600,000 to cover all professional and institutional services associated with an admission of a TRICARE/CHAMPUS-eligible patient under the DVHIP Protocol II. The VAPAHCS shall be responsible for collecting the beneficiary cost-shares from the TRICARE/CHAMPUS-eligible patients. No deductible shall apply for inpatient services provided to TRICARE/CHAMPUS-eligible patients.

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD (CONTINUED)

3. For individuals with TBI with dual VA and TRICARE/CHAMPUS eligibility, VAPAHCS shall be responsible for all care of such patients listed below under the DVHIP Protocol II. The VAPAHCS shall ensure that the care provided to the patients with dual eligibility listed below under the DVHIP is not billed to the DoD demonstration claims processor. With regard to the patients with dual VA and TRICARE/CHAMPUS eligibility, VAPAHCS shall be responsible for the following beneficiary care under the DVHIP until the enrollment system required by Public Law 104-262 is fully implemented:

a. care for mandatory/non-discretionary veterans
b. care for veterans for service-connected conditions

Upon implementation of that enrollment system, the VAPAHCS shall be responsible for veterans who are enrolled or who may be provided care from VA because they are exempt from enrollment.

4. For individuals without VA eligibility who appear to meet the inclusion criteria in the DVHIP Protocol II, VAPAHCS shall refer such patients to the DoD demonstration claims processor, namely, Palmetto Government Benefits Administrators (PGBA), for TRICARE/CHAMPUS eligibility verification on the Defense Enrollment Eligibility Reporting System (DEERS). The toll free telephone number for PGBA is 1-800-779-3060 and the address is:

PGBA
DVHIP Demonstration Project
P.O. Box 100514
Florence, SC 29501-0514

Upon receipt of a written/faxed TRICARE/CHAMPUS eligibility verification of a beneficiary from PGBA, VAPAHCS shall furnish inpatient services to the beneficiary in accordance with the DVHIP Protocol II.

5. VAPAHCS shall be responsible for obtaining information regarding possible third party liability and other health insurance (OHI) coverage of the TRICARE/CHAMPUS beneficiary.

(1) VAPAHCS shall collect from the third party or the OHI in accordance with VA procedures and bill any remaining balance of the total per diem amount to the demonstration claims processor within thirty (30) days of the receipt of the payment from the OHI. VAPAHCS shall ensure proper entry regarding the OHI on the.

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD (CONTINUED)

UB-92 claim form before submitting the claim form to the demonstration claims processor.

(2) In the event that VAPAHCS is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill shall be presented by VAPAHCS to the demonstration claims processor.

6. The VAPAHCS shall submit claims for TRICARE/CHAMPUS-eligible patients for inpatient care under the DVHIP Protocol II based on the per diem rate (paragraph 2) on a UB-92 claim form to the DoD demonstration claims processor at the address provided in paragraph 4, above. The DoD agrees to waive the billing itemization requirements.

7. For a TRICARE/CHAMPUS-eligible patient, the VAPAHCS shall submit one claim for billing for the initial inpatient evaluation, rehabilitation care, and the initial post-discharge evaluation within thirty (30) calendar days upon completion of the initial post-discharge evaluation. Claims for admissions at 6-, 12-, and 24-month follow-ups shall be submitted by VAPAHCS within thirty (30) calendar days of completion of each follow-up evaluation. In a case where care of a TRICARE/CHAMPUS-eligible patient is terminated during or after the initial inpatient evaluation or prior to completion of the treatment under the DVHIP Protocol II, the VAPAHCS shall submit the claim within thirty (30) calendar days of such termination.

8. The VAPAHCS shall appoint a social worker/case manager to assist the TRICARE/CHAMPUS beneficiaries in placement following discharge to ensure they receive the full benefit of any available health care entitlements.

9. In the event that a TRICARE/CHAMPUS-eligible patient receives care from the VAPAHCS and the care is determined not to be authorized under the DVHIP Protocol II, the VAPAHCS shall hold the TRICARE/CHAMPUS-eligible patient harmless for any cost of the care.

10. The VAPAHCS and the DoD demonstration claims processor (paragraph 4) shall establish points of contact who shall be familiar with this MOU and the TRICARE/CHAMPUS instructions regarding the DVHIP demonstration project. The points of contact shall assist in resolving claims, billings, DEERS eligibility verification, and other related issues as they arise.

11. Unless otherwise agreed between the VAPAHCS and TRICARE Support Office/OCHAMPUS, the VAPAHCS shall provide coordination support on any billing

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD (CONTINUED)

and demonstration related issues for up to 12 months after termination of the demonstration. Unless otherwise directed by TRICARE Support Office/OCHAMPUS, the DoD claims processor shall provide the claims processing support for up to 12 months after termination of the demonstration.

IV. ADMINISTRATIVE AND CLINICAL RESPONSIBILITIES

The Assistant Secretary of Defense for Health Affairs, in consultation with the Under Secretary for Health of the Department of Veterans Affairs, shall conduct overall program management relating to this MOU and the DVHIP.

V. ISSUE RESOLUTION

Throughout the course of this agreement, issues involving interpretation of its provisions, unanticipated technical matters, and proposed modifications in the interest of equity can be expected. The Departments agree to work together in a collegial manner and in good faith to resolve such issues in a manner that is fair, equitable, supportive of the objectives of the pertinent laws, and responsive to the needs of VA and DoD beneficiaries.

VI. POINTS OF CONTACT

a. For the Department of Veterans Affairs:

Arthur S. Hamerschlag
Director, Medical Sharing Office (166)
Department of Veterans Affairs
Washington, DC 20420
(202) 273-8403

Elaine S. Date, M.D.
Local Principal Investigator
VAPAHCS
Palo Alto, CA 94304
(415) 852-3206

b. For the Department of Defense:

Margaret Orcutt, CAPT, MC, USN
Director, Clinical Consultation
Office of the Assistant Secretary of Defense (Health Affairs)
1200 Defense Pentagon
Room 3D368
Washington, DC 20301-1200
(703) 695-6800

Andres M. Salazar, COL, MC, USA (Ret)
Director, DVHIP
Bldg. 7, Room 224
Walter Reed Army Medical Center
Washington, DC 20307
(202) 782-6345

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD (CONTINUED)

VII. MODIFICATION OR TERMINATION

a. Either the VA or DoD may propose amendments modifying this agreement at any time. Before any amendment shall become effective, both parties must agree in writing to the modification. The effective date of any amendments shall be the date agreed upon and specified in the agreement, or, if no date is specified, the last date upon which representative officials of both parties have agreed in writing to the amendment.

b. This MOU terminates (1) upon completion of the DVHIP Protocol II study which is projected to last for three years, or (2) may be terminated at any date upon 60 days notice in writing to the other party.

VIII. EFFECTIVE DATE

August 1, 1997.

FIGURE 23-4-1 MOU BETWEEN THE DEPARTMENT OF VA PALO ALTO HEALTH CARE SYSTEM AND DOD (CONTINUED)

James A. Goff, FACHE
Director
Veterans Affairs Palo Alto Health Care System
Palo Alto, California

Date AUG 2 8 1996

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs

Date 05/23/97

Edward D. Martin, M.D.
Acting Assistant Secretary of Defense
for Health Affairs

Date JUN 2 0 1997

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
MINNEAPOLIS, MINNESOTA
AND
THE DEPARTMENT OF DEFENSE

SUBJECT: Care of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE Beneficiaries in the Veterans Affairs Medical Center (VAMC), Minneapolis, Minnesota, under the Defense and Veterans Head Injury Program Protocol II.

I. PURPOSE

This Memorandum of Understanding (MOU) is to establish guidance for inpatient care for TRICARE/CHAMPUS beneficiaries in the VAMC, Minneapolis, Minnesota (hereinafter referred to as "VAMC"), under a demonstration project in which the Department of Defense (DoD) will participate in the DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) PROTOCOL II TRAUMATIC BRAIN INJURY (TBI) REHABILITATION: A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARAMACOTHERAPY.

II. AUTHORITY

This MOU is authorized by Section 201 of the Veterans Health Care Act of 1992, Pub. L. 102-585, 38 U.S.C. 8111, and 10 U.S.C. 1104.

III. POLICY

1. Effective August 1, 1997, the VAMC shall provide inpatient services for TBI for the TRICARE/CHAMPUS-eligible patients according to the DVHIP Protocol II dated December 23, 1994 (attached).

2. The DoD shall reimburse VAMC based on a negotiated per diem rate of $600,000 to cover all professional and institutional services associated with an admission of a TRICARE/CHAMPUS-eligible patient under the DVHIP Protocol II. The VAMC shall be responsible for collecting the beneficiary cost-shares from the TRICARE/CHAMPUS-eligible patients. No deductible shall apply for inpatient services provided to TRICARE/CHAMPUS-eligible patients.

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD (CONTINUED)

3. For individuals with TBI with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for all care of such patients listed below under the DVHIP Protocol II. The VAMC shall ensure that the care provided to the patients with dual eligibility listed below under the DVHIP is not billed to the DoD demonstration claims processor. With regard to the patients with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for the following beneficiary care under the DVHIP until the enrollment system required by Public Law 104-262 is fully implemented:

a. care for mandatory/non-discretionary veterans
b. care for veterans for service-connected conditions

Upon implementation of that enrollment system, the VAMC shall be responsible for veterans who are enrolled or who may be provided care from VA because they are exempt from enrollment.

4. For individuals without VA eligibility who appear to meet the inclusion criteria in the DVHIP Protocol II, VAMC shall refer such patients to the DoD demonstration claims processor, namely, Palmetto Government Benefits Administrators (PGBA), for TRICARE/CHAMPUS eligibility verification on the Defense Enrollment Eligibility Reporting System (DEERS). The toll free telephone number for PGBA is 1-800-779-3060 and the address is:

PGBA
DVHIP Demonstration Project
P.O. Box 100514
Florence, SC 29501-0514

Upon receipt of a written/faxed TRICARE/CHAMPUS eligibility verification of a beneficiary from PGBA, VAMC shall furnish inpatient services to the beneficiary in accordance with the DVHIP Protocol II.

5. Participating VAMC shall be responsible for obtaining information regarding possible third party liability and other health insurance (OHI) coverage of the TRICARE/CHAMPUS beneficiary.

(1) The VAMC shall collect from the third party or the OHI in accordance with VA procedures and bill any remaining balance of the total per diem amount to the demonstration claims processor within thirty (30) days of the receipt of the payment from the OHI. The VAMC shall ensure proper entry regarding the OHI on the

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD (CONTINUED)

UB-92 claim form before submitting the claim form to the demonstration claims processor.

(2) In the event that the VAMC is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill shall be presented by the VAMC to the demonstration claims processor.

6. The VAMC shall submit claims for TRICARE/CHAMPUS-eligible patients for inpatient care under the DVHIP Protocol II based on the per diem rate (paragraph 2) on a UB-92 claim form to the DoD demonstration claims processor at the address provided in paragraph 4, above. The DoD agrees to waive the billing itemization requirements.

7. For a TRICARE/CHAMPUS-eligible patient, the VAMC shall submit one claim for billing for the initial inpatient evaluation, rehabilitation care, and the initial post-discharge evaluation within thirty (30) calendar days upon completion of the initial post-discharge evaluation. Claims for admissions at 6-, 12-, and 24-month follow-ups shall be submitted by VAMC within thirty (30) calendar days of completion of each follow-up evaluation. In a case where care of a TRICARE/CHAMPUS-eligible patient is terminated during or after the initial inpatient evaluation or prior to completion of the treatment under the DVHIP Protocol II, the VAMC shall submit the claim within thirty (30) calendar days of such termination.

8. The VAMC shall appoint a social worker/case manager to assist the TRICARE/CHAMPUS beneficiaries in placement following discharge to ensure they receive the full benefit of any available health care entitlements.

9. In the event that a TRICARE/CHAMPUS-eligible patient receives care from the VAMC and the care is determined not to be authorized under the DVHIP Protocol II, the VAMC shall hold the TRICARE/CHAMPUS-eligible patient harmless for any cost of the care.

10. The VAMC and the DoD demonstration claims processor (paragraph 4) shall establish points of contact who shall be familiar with this MOU and the TRICARE/CHAMPUS instructions regarding the DVHIP demonstration project. The points of contact shall assist in resolving claims, billings, DEERS eligibility verification, and other related issues as they arise.

11. Unless otherwise agreed between the VAMC and TRICARE Support Office/OCHAMPUS, the VAMC shall provide coordination support on any billing and

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD (CONTINUED)

demonstration related issues for up to 12 months after termination of the demonstration. Unless otherwise directed by TRICARE Support Office/OCHAMPUS, the DoD claims processor shall provide the claims processing support for up to 12 months after termination of the demonstration.

IV. ADMINISTRATIVE AND CLINICAL RESPONSIBILITIES

The Assistant Secretary of Defense for Health Affairs, in consultation with the Under Secretary for Health of the Department of Veterans Affairs, shall conduct overall program management relating to this MOU and the DVHIP.

V. ISSUE RESOLUTION

Throughout the course of this agreement, issues involving interpretation of its provisions, unanticipated technical matters, and proposed modifications in the interest of equity can be expected. The Departments agree to work together in a collegial manner and in good faith to resolve such issues in a manner that is fair, equitable, supportive of the objectives of the pertinent laws, and responsive to the needs of VA and DoD beneficiaries.

VI. POINTS OF CONTACT

a. For the Department of Veterans Affairs:

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(612) 725-2000 x2044

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Margaret Orcutt, CAPT, MC, USN
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(202) 782-6345

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD (CONTINUED)

VII. MODIFICATION OR TERMINATION

a. Either the VA or DoD may propose amendments modifying this agreement at any time. Before any amendment shall become effective, both parties must agree in writing to the modification. The effective date of any amendments shall be the date agreed upon and specified in the agreement, or, if no date is specified, the last date upon which representative officials of both parties have agreed in writing to the amendment.

b. This MOU terminates (1) upon completion of the DVHIP Protocol II study which is projected to last for three years, or (2) may be terminated at any date upon 60 days notice in writing to the other party.

VIII. EFFECTIVE DATE

August 1, 1997.

FIGURE 23-4-2 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER MINNEAPOLIS, MINNESOTA AND DOD (CONTINUED)

Charles A. Milbrandt, FACHE
Director
VA Medical Center
Minneapolis, Minnesota

Date 5/8/96

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs

Date 05/23/97

Edward D. Martin, M.D.
Acting Assistant Secretary of Defense
for Health Affairs

Date JUN 20 1997

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
RICHMOND, VIRGINIA
AND
THE DEPARTMENT OF DEFENSE

SUBJECT: Care of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE Beneficiaries in the Veterans Affairs Medical Center (VAMC), Richmond, Virginia, under the Defense and Veterans Head Injury Program Protocol II.

I. PURPOSE

This Memorandum of Understanding (MOU) is to establish guidance for inpatient care for TRICARE/CHAMPUS beneficiaries in the VAMC, Richmond, Virginia (hereinafter referred to as "VAMC"), under a demonstration project in which the Department of Defense (DoD) will participate in the DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) PROTOCOL II TRAUMATIC BRAIN INJURY (TBI) REHABILITATION: A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARAMACOTHERAPY.

II. AUTHORITY

This MOU is authorized by Section 201 of the Veterans Health Care Act of 1992, Pub. L. 102-585, 38 U.S.C. 8111, and 10 U.S.C. 1104.

III. POLICY

1. Effective August 1, 1997, the VAMC shall provide inpatient services for TBI for the TRICARE/CHAMPUS-eligible patients according to the DVHIP Protocol II dated December 23, 1994 (attached).

2. The DoD shall reimburse VAMC based on a negotiated per diem rate of $600,000 to cover all professional and institutional services associated with an admission of a TRICARE/CHAMPUS-eligible patient under the DVHIP Protocol II. The VAMC shall be responsible for collecting the beneficiary cost-shares from the TRICARE/CHAMPUS-eligible patients. No deductible shall apply for inpatient services provided to TRICARE/CHAMPUS-eligible patients.

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD (CONTINUED)

3. For individuals with TBI with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for all care of such patients listed below under the DVHIP Protocol II. The VAMC shall ensure that the care provided to the patients with dual eligibility listed below under the DVHIP is not billed to the DoD demonstration claims processor. With regard to the patients with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for the following beneficiary care under the DVHIP until the enrollment system required by Public Law 104-262 is fully implemented:

a. care for mandatory/non-discretionary veterans
b. care for veterans for service-connected conditions

Upon implementation of that enrollment system, the VAMC shall be responsible for veterans who are enrolled or who may be provided care from VA because they are exempt from enrollment.

4. For individuals without VA eligibility who appear to meet the inclusion criteria in the DVHIP Protocol II, VAMC shall refer such patients to the DoD demonstration claims processor, namely, Palmetto Government Benefits Administrators (PGBA), for TRICARE/CHAMPUS eligibility verification on the Defense Enrollment Eligibility Reporting System (DEERS). The toll free telephone number for PGBA is 1-800-779-3060 and the address is:

PGBA
DVHIP Demonstration Project
P.O. Box 100514
Florence, SC 29501-0514

Upon receipt of a written/faxed TRICARE/CHAMPUS eligibility verification of a beneficiary from PGBA, VAMC shall furnish inpatient services to the beneficiary in accordance with the DVHIP Protocol II.

5. Participating VAMC shall be responsible for obtaining information regarding possible third party liability and other health insurance (OHI) coverage of the TRICARE/CHAMPUS beneficiary.

(1) The VAMC shall collect from the third party or the OHI in accordance with VA procedures and bill any remaining balance of the total per diem amount to the demonstration claims processor within thirty (30) days of the receipt of the payment from the OHI. The VAMC shall ensure proper entry regarding the OHI on the

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD (CONTINUED)

UB-92 claim form before submitting the claim form to the demonstration claims processor.

(2) In the event that the VAMC is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill shall be presented by the VAMC to the demonstration claims processor.

6. The VAMC shall submit claims for TRICARE/CHAMPUS-eligible patients for inpatient care under the DVHIP Protocol II based on the per diem rate (paragraph 2) on a UB-92 claim form to the DoD demonstration claims processor at the address provided in paragraph 4, above. The DoD agrees to waive the billing itemization requirements.

7. For a TRICARE/CHAMPUS-eligible patient, the VAMC shall submit one claim for billing for the initial inpatient evaluation, rehabilitation care, and the initial post-discharge evaluation within thirty (30) calendar days upon completion of the initial post-discharge evaluation. Claims for admissions at 6-, 12-, and 24-month follow-ups shall be submitted by VAMC within thirty (30) calendar days of completion of each follow-up evaluation. In a case where care of a TRICARE/CHAMPUS-eligible patient is terminated during or after the initial inpatient evaluation or prior to completion of the treatment under the DVHIP Protocol II, the VAMC shall submit the claim within thirty (30) calendar days of such termination.

8. The VAMC shall appoint a social worker/case manager to assist the TRICARE/CHAMPUS beneficiaries in placement following discharge to ensure they receive the full benefit of any available health care entitlements.

9. In the event that a TRICARE/CHAMPUS-eligible patient receives care from the VAMC and the care is determined not to be authorized under the DVHIP Protocol II, the VAMC shall hold the TRICARE/CHAMPUS-eligible patient harmless for any cost of the care.

10. The VAMC and the DoD demonstration claims processor (paragraph 4) shall establish points of contact who shall be familiar with this MOU and the TRICARE/CHAMPUS instructions regarding the DVHIP demonstration project. The points of contact shall assist in resolving claims, billings, DEERS eligibility verification, and other related issues as they arise.

11. Unless otherwise agreed between the VAMC and TRICARE Support Office/OCHAMPUS, the VAMC shall provide coordination support on any billing and

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD (CONTINUED)

demonstration related issues for up to 12 months after termination of the demonstration. Unless otherwise directed by TRICARE Support Office/OCHAMPUS, the DoD claims processor shall provide the claims processing support for up to 12 months after termination of the demonstration.

IV. ADMINISTRATIVE AND CLINICAL RESPONSIBILITIES

The Assistant Secretary of Defense for Health Affairs, in consultation with the Under Secretary for Health of the Department of Veterans Affairs, shall conduct overall program management relating to this MOU and the DVHIP.

V. ISSUE RESOLUTION

Throughout the course of this agreement, issues involving interpretation of its provisions, unanticipated technical matters, and proposed modifications in the interest of equity can be expected. The Departments agree to work together in a collegial manner and in good faith to resolve such issues in a manner that is fair, equitable, supportive of the objectives of the pertinent laws, and responsive to the needs of VA and DoD beneficiaries.

VI. POINTS OF CONTACT

a. For the Department of Veterans Affairs:

Arthur S. Hamerschlag
Director, Medical Sharing Office (166)
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Washington, DC 20420
(202) 273-8403

Charles R. Lamb, M.D.
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b. For the Department of Defense:

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Director, Clinical Consultation
Office of the Assistant Secretary of Defense (Health Affairs)
1200 Defense Pentagon
Room 3D368
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(703) 695-6800

Andres M. Salazar, COL, MC, USA (Ret)
Director, DVHIP
Bldg. 7, Room 224
Walter Reed Army Medical Center
Washington, DC 20307
(202) 782-6345

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD (CONTINUED)

VII. MODIFICATION OR TERMINATION

a. Either the VA or DoD may propose amendments modifying this agreement at any time. Before any amendment shall become effective, both parties must agree in writing to the modification. The effective date of any amendments shall be the date agreed upon and specified in the agreement, or, if no date is specified, the last date upon which representative officials of both parties have agreed in writing to the amendment.

b. This MOU terminates (1) upon completion of the DVHIP Protocol II study which is projected to last for three years, or (2) may be terminated at any date upon 60 days notice in writing to the other party.

VIII. EFFECTIVE DATE

August 1, 1997.

FIGURE 23-4-3 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER RICHMOND, VIRGINIA AND DOD (CONTINUED)

James W. Dudley
Director
VA Medical Center
Richmond, Virginia

Date 6/20/96

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs

Date 05/23/97

Stephen C. Joseph, M.D., M.P.H.
Assistant Secretary of Defense
for Health Affairs

Date FEB 4 1997

FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD

MEMORANDUM OF UNDERSTANDING
BETWEEN
THE DEPARTMENT OF VETERANS AFFAIRS MEDICAL CENTER
TAMPA, FLORIDA
AND
THE DEPARTMENT OF DEFENSE

SUBJECT: Care of the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS)/TRICARE Beneficiaries in the Veterans Affairs Medical Center (VAMC), Tampa, Florida, under the Defense and Veterans Head Injury Program Protocol II.

I. PURPOSE

This Memorandum of Understanding (MOU) is to establish guidance for inpatient care for TRICARE/CHAMPUS beneficiaries in the VAMC, Tampa, Florida (hereinafter referred to as "VAMC"), under a demonstration project in which the Department of Defense (DoD) will participate in the DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) PROTOCOL II TRAUMATIC BRAIN INJURY (TBI) REHABILITATION: A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARAMACOTHERAPY.

II. AUTHORITY

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III. POLICY

1. Effective August 1, 1997, the VAMC shall provide inpatient services for TBI for the TRICARE/CHAMPUS-eligible patients according to the DVHIP Protocol II dated December 23, 1994 (attached).

2. The DoD shall reimburse VAMC based on a negotiated per diem rate of $600,000 to cover all professional and institutional services associated with an admission of a TRICARE/CHAMPUS-eligible patient under the DVHIP Protocol II. The VAMC shall be responsible for collecting the beneficiary cost-shares from the TRICARE/CHAMPUS-eligible patients. No deductible shall apply for inpatient services provided to TRICARE/CHAMPUS-eligible patients.

FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD (CONTINUED)

3. For individuals with TBI with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for all care of such patients listed below under the DVHIP Protocol II. The VAMC shall ensure that the care provided to the patients with dual eligibility listed below under the DVHIP is not billed to the DoD demonstration claims processor. With regard to the patients with dual VA and TRICARE/CHAMPUS eligibility, VAMC shall be responsible for the following beneficiary care under the DVHIP until the enrollment system required by Public Law 104-262 is fully implemented:

a. care for mandatory/non-discretionary veterans
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Upon implementation of that enrollment system, the VAMC shall be responsible for veterans who are enrolled or who may be provided care from VA because they are exempt from enrollment.

4. For individuals without VA eligibility who appear to meet the inclusion criteria in the DVHIP Protocol II, VAMC shall refer such patients to the DoD demonstration claims processor, namely, Palmetto Government Benefits Administrators (PGBA), for TRICARE/CHAMPUS eligibility verification on the Defense Enrollment Eligibility Reporting System (DEERS). The toll free telephone number for PGBA is 1-800-779-3060 and the address is:

PGBA
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P.O. Box 100514
Florence, SC 29501-0514

Upon receipt of a written/faxed TRICARE/CHAMPUS eligibility verification of a beneficiary from PGBA, VAMC shall furnish inpatient services to the beneficiary in accordance with the DVHIP Protocol II.

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FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD (CONTINUED)

UB-92 claim form before submitting the claim form to the demonstration claims processor.

(2) In the event that the VAMC is unable to collect from a third party or the OHI for health care services that would be covered under the third party liability or by the OHI if provided by a private provider, no bill shall be presented by the VAMC to the demonstration claims processor.

6. The VAMC shall submit claims for TRICARE/CHAMPUS-eligible patients for inpatient care under the DVHIP Protocol II based on the per diem rate (paragraph 2) on a UB-92 claim form to the DoD demonstration claims processor at the address provided in paragraph 4, above. The DoD agrees to waive the billing itemization requirements.

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10. The VAMC and the DoD demonstration claims processor (paragraph 4) shall establish points of contact who shall be familiar with this MOU and the TRICARE/CHAMPUS instructions regarding the DVHIP demonstration project. The points of contact shall assist in resolving claims, billings, DEERS eligibility verification, and other related issues as they arise.

11. Unless otherwise agreed between the VAMC and TRICARE Support Office/OCHAMPUS, the VAMC shall provide coordination support on any billing and

FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD (CONTINUED)

demonstration related issues for up to 12 months after termination of the demonstration. Unless otherwise directed by TRICARE Support Office/OCHAMPUS, the DoD claims processor shall provide the claims processing support for up to 12 months after termination of the demonstration.

IV. ADMINISTRATIVE AND CLINICAL RESPONSIBILITIES

The Assistant Secretary of Defense for Health Affairs, in consultation with the Under Secretary for Health of the Department of Veterans Affairs, shall conduct overall program management relating to this MOU and the DVHIP.

V. ISSUE RESOLUTION

Throughout the course of this agreement, issues involving interpretation of its provisions, unanticipated technical matters, and proposed modifications in the interest of equity can be expected. The Departments agree to work together in a collegial manner and in good faith to resolve such issues in a manner that is fair, equitable, supportive of the objectives of the pertinent laws, and responsive to the needs of VA and DoD beneficiaries.

VI. POINTS OF CONTACT

a. For the Department of Veterans Affairs:

Arthur S. Hamerschlag
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Washington, DC 20307
(202) 782-6345

FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD (CONTINUED)

VII. MODIFICATION OR TERMINATION

a. Either the VA or DoD may propose amendments modifying this agreement at any time. Before any amendment shall become effective, both parties must agree in writing to the modification. The effective date of any amendments shall be the date agreed upon and specified in the agreement, or, if no date is specified, the last date upon which representative officials of both parties have agreed in writing to the amendment.

b. This MOU terminates (1) upon completion of the DVHIP Protocol II study which is projected to last for three years, or (2) may be terminated at any date upon 60 days notice in writing to the other party.

VIII. EFFECTIVE DATE

August 1, 1997.

FIGURE 23-4-4 MOU BETWEEN THE DEPARTMENT OF VA MEDICAL CENTER TAMPA, FLORIDA AND DOD (CONTINUED)

Richard A. Silver
Director
VA Medical Center
Tampa, Florida

Date 6-10-96

Kenneth W. Kizer, M.D., M.P.H.
Under Secretary for Health
Department of Veterans Affairs

Date 05/23/97

Edward D. Martin, M.D.
Acting Assistant Secretary of Defense
for Health Affairs

Date JUN 20 1997

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II

(This is an attachment to each MOU.)

DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP)
PROTOCOL II

TRAUMATIC BRAIN INJURY REHABILITATION:
A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO
INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARMACOTHERAPY

Principal Investigator
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Donald L. MacLennan, M.A., Minneapolis VAMC
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Linda Picon-Nieto, MC.D., Tampa VAMC
Glenn Curtiss, Ph.D., Tampa VAMC
Alexander K. Ommaya, M.A., DVHIP
Deana Haggerty, M.S., Richmond VAMC
Valerie Burgess, M.S., CCC-SLP, Richmond VAMC
and the DVHIP Study Group

December 23, 1994

Attachment to MOU

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

PROBLEM TO BE INVESTIGATED

Traumatic brain injury (TBI) is the principal cause of death and disability in Americans under age 35, with consequences ranging from physical to long-term cognitive, behavioral, and social deficits. Total cost in the United States is conservatively estimated at $39 billion per year. Survivors of TBI tend to manifest specific patterns of impairment, which distinguish them from stroke or other neurologically impaired patients. While there is general consensus that some level of TBI-specific rehabilitation is beneficial, the exact nature and timing of the rehabilitation elements which are best for a given patient remain highly controversial. Most rehabilitation strategies, although often very expensive, have not been subjected to the degree of scientific scrutiny for effectiveness and cost efficiency which has been
expected of other medical therapies.

HYPOTHESES

1. In moderate to severe TBI survivors, a comprehensive postacute rehabilitation program focusing on specific impaired cognitive processes will differ by at least 15% in ultimate patient functional outcome from one with a more functional orientation.
2. Such a cognitive rehabilitation program will improve performance on measures of specific cognitive abilities when compared to a more functional orientation.
3. Patients who receive sertraline in combination with their rehabilitation will have significantly better outcome than those who receive placebo.
4. Exploratory Hypotheses
   a. Apathetic, nondepressed TBI survivors who receive the stimulant methylphenidate in combination with their rehabilitation will have better outcome than those who receive placebo.
   b. Specific subsets of TBI patients (i.e., depressed or agitated patients) will receive more benefit from sertraline than those without depression or agitation.
   c. Specific subsets of TBI patients will receive more benefit than others from either cognitive or functional therapy.

OBJECTIVES

1. To evaluate the effectiveness and relative cost efficiency of two alternative TBI rehabilitation strategies.
2. To evaluate the effectiveness of sertraline as an adjuvant to two alternative TBI rehabilitation strategies.
3. To further develop and validate outcome measures which define the short-term and long-term neurologic, cognitive, behavioral, and psychosocial consequences of moderate to severe TBI.

MEDICAL APPLICATION

The military loses thousands of man-years in experience and hundreds of thousands of training and education dollars each year due to effects of traumatic brain injuries in soldiers prematurely returned to active duty or separated outright. Many young adults never return to premorbid skills or responsibilities after TBI, despite intensive and comprehensive rehabilitation efforts on their behalf. On the other hand, many others with similar injuries successfully return to active lives, if not premorbid levels, with little or no systematic rehabilitation. TBI rehabilitation is labor intensive, expensive, and emotionally demanding of patient and staff alike. A major long-term goal of this program will be to determine the effectiveness and relative cost efficiency of alternative TBI rehabilitation strategies and to define optimal care for survivors of TBI.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Background/Status

There is about one TBI hospitalization per minute in the USA, at an estimated overall cost of some $39 billion per year.[1, 2] Similarly, TBI accounts for over 40% of fatalities and at least 14% of surviving casualties in combat and for a disproportionate amount of acute and long-term combat casualty care resources. In peacetime, there are over 8,000 TBI hospitalizations in Department of Defense (DoD) and Department of Veterans Affairs (DVA) hospitals each year. These peacetime injuries are similar in nature and cause to those occurring in the general civilian population. Over the past two decades, we have come to recognize that it is usually inappropriate and counterproductive to lump the postacute management of TBI with that of other neurologic disabilities, and that most TBI patients would benefit from at least some level of specialized, interdisciplinary rehabilitation. In that time, there has been a rapid growth of mostly private and often very expensive TBI rehabilitation programs throughout the nation. These have filled a vacuum in TBI care, but the exact form and intensity of TBI rehabilitation required for a given patient remains highly controversial. Few, if any, programs or program elements have been subjected to the degree of scientific scrutiny for efficacy and cost efficiency that is usually applied to other medical treatments. In particular, the remarkable ability of the young adult brain to compensate for injury naturally has often not been considered in the evaluation of outcome from various treatments. For example, over 55% of moderate to severe head injured Vietnam veterans were gainfully employed some 15 years post injury with no formal TBI rehabilitation.[3]

The relative paucity of scientific program evaluation has in turn made it difficult to focus rehabilitation efforts on those elements most likely to return the patient to independent living and/or gainful employment. Some institutional programs may even be counterproductive, particularly if they inadvertently foster continued dependence in the patient.

Concepts regarding the ideal form for a TBI rehabilitation program are rapidly changing. Functional areas which usually are addressed in comprehensive rehabilitation programs include: mobility, activities of daily living, speech, language and communication, cognitive or mental processes, and behavior and social interaction. Depending on the focus of the program, certain areas may be emphasized or de-emphasized in any given program. While there tends to be reasonable consensus in approaches to the rehabilitation of mobility and activities of daily living, wide variability exists in the rehabilitation of communication, cognitive processes, behavior and social interaction and work skills.

At least three alternative, yet overlapping, TBI rehabilitation strategies have evolved, all of which attend to basic mobility, activities of daily living, and traditionally recognized speech and language deficits in a similar manner. The first, and perhaps most widespread, strategy seeks to identify and target further specific cognitive, behavioral, communication, or other deficits for individual therapy.[4, 5, 6, 7] Such programs generally involve interdisciplinary evaluation and intensive individual or small group intervention in an inpatient therapeutic setting. The second approach does not emphasize targeting of such specific deficits, but assumes that most functional impairments will improve as the patient is provided the opportunity to practice appropriate function in a supportive rehabilitation environment. The third strategy involves the use of adjuvant psychotropic medications to improve performance during the rehabilitation process and beyond.

Cognitive Rehabilitation

Cognitive rehabilitation of TBI survivors is one of the more controversial elements of the first approach. The underlying assumption is that cognitive and behavioral deficits are the basic cause of the ultimate psychosocial dysfunction, and their rehabilitation will result in cognitive reorganization with a generalized improvement in overall function. At least four basic subareas can be defined within the concept of "*cognitive rehabilitation*" for TBI. These are: (1) memory, (2) executive functions, (3) attention, and (4) pragmatic communication. Prospective memory is the ability to learn information, retain it across time, and retrieve it at the appropriate time, while working memory is a subsystem for temporary storage and manipulation of information. Executive functions include self-awareness, self-cueing, reasoning, and problem-solving skills, and the ability to monitor and control one's performance. Attention processes include the ability to focus attention, to shift and/or divide

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

attention, and to sustain attention on a selected stimulus. Pragmatic communication refers to those behaviors which have the potential, if used inappropriately, to disrupt or penalize conversational interchanges. Such impairments may or may not include traditionally recognized speech and language deficits, and are often seen after TBI. Pragmatics includes interactive behaviors such as initiation of conversation, topic management, turn taking, modulation of voice volume and prosody, verbal organization, and active listening.

These four cognitive elements obviously interact. For example, attention is strongly associated with the current concept of working memory[8] in which a central *"memory executive"* allows for temporary storage of information while attention is shifted to other tasks. Thus, while cognitive rehabilitation can be divided into various elements, they should all be considered part of an interdependent system.

We have built therapeutic modules around each of these four basic elements, and within each module; tasks are arranged hierarchically from simple to complex, depending on the Rancho Los Amigos cognitive level of a given patient. (Appendix A) For example, intervention for lower level patients would be centered on environmental modification, while higher level patients would undergo training of specific skills and/or remediation of underlying cognitive deficits. In addition, basic occupational, physical, and speech therapies will be utilized as needed to treat specific inpairments.

Functional TBI Rehabilitation

The second approach is more empirical, also utilizing basic occupational therapy (OT), physical therapy (PT), and speech therapies as needed, but focusing on overall functional outcome.[9] It generally assumes that specific physical, cognitive, speech, and behavioral impairments will recover better when practiced in a therapeutic setting representative of the social environment to which the patient will return. It relies on traditional physical, occupational, and speech therapies supplemented by recreational and group therapies. Such functional programs tend to be less labor intensive, and thus initially less expensive than cognitive therapies. This approach reflects current practice at various facilities around the country, and thus reflects a more traditional approach to inpatient TBI rehabilitation.

Prior to the development of *"cognitive remediation"*, and despite methodological difficulties, uncontrolled studies first indicated that a interdisciplinary inpatient rehabilitation approach seemed to improve outcome in these patients,[10, 11, 12, 13] and that patients with severe head injuries benefited more from early versus late inpatient rehabilitation. Only one study has compared brain-injured patients who underwent rehabilitation to patients who did not, but interpretation of results was complicated by differing injury severity in the two groups. After correcting for this difference, the authors suggested a possible benefit of general rehabilitation.[14] Inpatient rehabilitation in this study included *"cognitive therapy"*, but the nature or extent of this therapy was not described. It is doubtful that it was similar to current notions of cognitive remediation because the study sample was collected in 1977 and 1979, when cognitive remediation was in the early stages of development.

We have surveyed directors, case managers, and therapists from various brain injury programs and discovered a high degree of uniformity between sites in the amount and types of therapies offered. All sites surveyed easily surpassed the minimum requirements of JCAHO, which state that a *"comprehensive physical rehabilitation program or unit directly provides, at a minimum: rehabilitation medicine, rehabilitation nursing, social work, occupational therapy, physical therapy, and speech-language pathology services"*.[15] Other services, such as recreational therapy, neuropsychological rehabilitation, prosthetics, and vocational rehabilitation may be offered, but are not considered necessary for accreditation.

The details of what therapists actually do are more difficult to establish, but based on responses to our questionnaire, this also appeared to be relatively uniform. However, much of what therapists do with patients is still intuitive, supportive, and a reflection of their own style and experience. For example, therapists from several disciplines used selected *"cognitive"* interventions routinely in their clinical practice. While for practical reasons it may thus be impossible at present to eliminate all variability between individual therapists, certain therapeutic guidelines will be necessary across centers in order

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

to ensure comparability of results and the ultimate validity of the study. Specifically, these guidelines will include isolation and restriction of cognitive rehabilitation training from the functional program patients without eliminations use of certain less specific, commonly accepted and routinely utilized cognitive rehabilitation techniques, such as memory books or helping patients learn to self-monitor and redirect cognitive processes. In addition, the total hours of therapy per week provided by a given discipline will be kept comparable within a specified range for each of the treatment arms (see Conduct of Study and Appendices below).

Pharmacological Therapies

Finally, a growing body of basic, as well as clinical, literature suggests that adjunctive pharmacological treatment will not only facilitate behavioral management during rehabilitation therapy, but may result in a better ultimate functional outcome. The basic premise is that TBI results in damage to adrenergic, dopaminergic, and/or serotonergic pathways and that such damage is in turn responsible for attention, motivation and other behavioral deficits. Use of adrenergic (dextroamphetamine, methylphenidate), dopaminergic (bromocriptine, amantadine), or serotonergic (buspirone, fluoxetine, sertraline) agonists has thus been variously proposed in TBI. The basic animal work of Feeney and colleagues has further supported the notion that combined use of such stimulants, plus rehabilitation, improves ultimate recovery.[16] Clinical support for the use of noradrenergic agonists to improve attention, concentration and behavioral measures derives from the experience with attention deficit disorder (ADD).[17] Single case design and placebo controlled TBI series have reported improved cognitive performance[18] or decreased anger[19] with methylphenidate and/or dextroamphetamine.[20] However, there is no clear persistent benefit with these drugs, and results remain mixed even though both have been in use for years in TBI patients. Their use appears most justified in sleepy or apathetic patients.

Interest in serotonergic drugs has been aroused by their usefulness in depression, as well as by the discovery of low CSF levels of the serotonin metabolite, 5-HIAA, in violent, impulsive patients[21] and in TBI patients with frontotemporal lesions. Thus, the combination of irritability, impulsivity, and decreased mood and motivation so commonly seen after TBI has been linked most closely to the serotonin system. In addition, serotonin's metabolite melatonin regulates circadian sleep rhythms which are commonly affected after TBI. Preliminary clinical studies with buspirone,[22] amytryptiline,[23] fluoxetine,[24] and sertraline[25,26] also support the use of serotonin agonists in TBI. Sertraline has been selected for this study as the safest, easiest to administer (once daily), most specific, and theoretically most promising of the neurotransmitter agonists available for TBI. The increased rate of organic depression often seen after TBI is further rationale for the use of a drug such as sertraline. However, there remains some controversy regarding the use of SSRIs in nondepressed, apathetic patients. In such patients, methylphenidate may be a preferable choice.[27]

In summary, all three rehabilitation strategies have been reported to increase the functional and independent living skills of TBI survivors, and decrease common neurobehavioral sequelae, such as cognitive slowing, mental inflexibility, impulsivity, and impoverished social skills. Several studies have reported that comprehensive brain injury rehabilitation speeds return to work after TBI, and increases patients' abilities to resume previous levels of vocational independence. In general, however, TBI rehabilitation outcome studies have been poorly controlled, if at all. Criticisms include their (1) lack of standardized interventions within or across settings; (2) unspecified, or unstandardized patient inclusions criteria; (3) lack of random assignment of patients to treatment conditions; (4) lack of meaningful, consistent, or focused outcome criteria; and (5) lack of standardized evaluation.[28, 29, 30, 31] As a result, the question remains as to whether and which interdisciplinary TBI rehabilitation approach is the most effective and cost efficient method of returning traumatic brain injured persons to maximum potential levels of community or vocational integration.

These questions are unlikely to be satisfactorily resolved other than by prospective, randomized, controlled clinical studies. The DoD and DVA health care systems offer a unique peacetime setting in which to address this national problem. Their populations are relatively uniform (young, healthy and

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

employed preinjury); and use of their existing facilities and medical networks will not only decrease costs considerably, but will allow for the standardization that is essential for proper multicenter studies.

The Defense and Veterans Head Injury Program (DVHIP) was established in response to a direct appropriation in the DoD Health Budget for FY92, in order to find solutions to the problem of TBI in the military and DVA; but the broader objective is to find solutions which are relevant to the national problem as well. At present the DVHIP includes eight regional military and DVA TBI centers, and a central office at the Uniformed Services University of the Health Sciences (USUHS) coordinating patient tracking, study design, data collection, and analysis. Another fundamental element of the program is a close collaboration with the National Head Injury Foundation's (NHIF) educational, family, and community integration activities. The present treatment protocol is one of the major controlled rehabilitation trials for TBI survivors to be undertaken by the DVHIP over the next several years.

STUDY DESIGN AND CONDUCT

All eligible patients will be randomized to one of four treatment groups. A factorial experimental design will be utilized in order to test simultaneously for the effects of rehabilitation approach and drug upon outcome in TBI patients. This design will permit us to evaluate the separate effects of treatment approach, drug, and their interactions. We hypothesize that the benefits of adjunctive drug therapy may be more pronounced in one rehabilitation approach than in the other.

Moderate to severe TBI patients will be randomized to a two ± 1 month comprehensive rehabilitation program emphasizing individual cognitive therapies, or to a more functional interdisciplinary rehabilitation program utilizing standard physical/occupational and speech therapies supplemented by recreational and group therapies. Patients will be simultaneously randomized to receive active drug or placebo during their respective inpatient program. The drug aspect of the protocol will be double-blinded and placebo controlled. After discharge, all patients will be referred to a facility near their home with specific recommendations for continued follow-up based on their residual level of disability. All of these programs will exceed the current Standard of Care (SOC) for most service members who have experienced recent head injury. Primary outcome measures will include functional independence and return to work/school, as well as specific quality of life, neurologic, neuropsychologic, EEG, and behavioral test variables.

PATIENTS

Inclusion Criteria

1. Moderate to severe closed head injury, manifested by admission GCS <12, PTA > 24 hours, or focal cerebral contusion on CT/MRI or Loss of Consciousness (LOC), > 12 hours.
2. Within three months of injury at randomization.
3. Rancho Los Amigos cognitive level of 5 - 7 at randomization.
4. Volunteer informed consent signed by patient or family.
5. Military or veterans health care beneficiary.
6. Age 17 - 55.

Exclusion Criteria

1. Unwillingness to participate in rehabilitation program or cooperate with investigators.
2. History of prior severe traumatic brain injury or other severe neurologic or psychiatric condition, such as psychosis, stroke, multiple sclerosis, or spinal cord injury.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

3. Any contraindication to the use of sertraline, or for apathetic patients, contraindications to the use of methylphenidate.

Given the coincidence of alcohol abuse and TBI exceeding 50% in some studies, alcohol or drug abusing subjects will not be excluded from the present protocol, but will be referred for substance abuse intervention in conjunction with their participation in this study. In addition, the randomization procedure will be monitored to ensure an even distribution of substance abuse patients to the treatment arms.

Similarly, it is likely that some patients will have received some formal rehabilitation prior to referral into this protocol. While it is not feasible to exclude such patients from specialized protocol treatment at this time, all such prior therapy will be recorded for subsequent analysis, and every attempt will be made to randomize patients early in their recovery course and before participation in extensive TBI rehabilitation programs elsewhere.

CONDUCT OF THE STUDY

Subjects will be admitted to one of four participating centers, where they will undergo a comprehensive standardized evaluation including neurologic, neuropsychologic, psychiatric, MRI, EEG, and psychosocial testing, and a functional PM&R assessment of adaptive skills. This initial testing will include two administrations, at least five days apart of the modified Marin Apathy Scale (Appendix C). Nondepressed apathetic patients (Marin score < 12) will be placed in group *"M"* (methylphenidate) for purposes of drug treatment randomization. All other patients will be in drug group *"S"* (sertraline). A diagnosis of depression for these purposes will be based on the formal psychiatric evaluation, including the Hamilton Depression Rating Scale and the Present State Examination.

Randomization

Following the comprehensive evaluation, nonapathetic patients (group *"S"*) will be randomly assigned to one of four groups:

Group A-1: Two months (± 1 month) of treatment in Rehabilitation Program A (focus on individual cognitive rehabilitation, Appendix A), with adjunct sertraline, 100 mg daily for six months.

Group A-2: Two months (± 1 month) of treatment in Rehabilitation Program A, with adjunct placebo for six months.

Group B-1: Two months (± 1 month) of treatment in Rehabilitation Program B (focus on functional rehabilitation, Appendix B), with adjunctive sertraline, 100 mg daily for six months as below.

Group B-2: Two months (± 1 month) of treatment in Rehabilitation Program B, with adjunct placebo for six months.

Similarly, in addition to being randomized into the cognitive or functional Rehabilitation Program, nondepressed apathetic patients (group *"M"*) will also be randomized to receive either methylphenidate, 10 mg, or placebo, b.i.d. for the duration of their inhospital rehabilitation.

A patient log will be kept on all head injury admissions to the study centers. If a patient is not randomized into the study, the study coordinator will record the reason. Patients will be randomly assigned to four groups as outlined above. The randomization scheme will use random permuted blocks, with blocking done for each center. Randomization will also be stratified by severity of injury (LOC 0 - 13 days, > 14 days) to ensure an even distribution of cases. Randomization will be done centrally, and assigned by telephone in the early stages of the study. After the patient signs the informed consent and enters the evaluation program, the study coordinator should notify the study

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

statistician, who will randomize the patient and communicate the randomization results upon completion of the patient's evaluation (in order to not bias the evaluation results). A screen for case eligibility (check of boxes) will be done by each center before randomization and mailed to the USUHS Central Office. (At later stages of the study, as patient flow increases, the centers may be provided randomization envelopes with instructions.) The pharmacy at each site will dispense drug or placebo according to the pharmacy randomization log, and maintain records of drug lots received and dispensed to patients.

Treatment Programs

The details of Rehabilitation Programs A and B are outlined in the appendices. Each program will be the responsibility of a separate team of therapists, who will function independently of each other, and of the outcome evaluation personnel. Each rehabilitation program will be structured so as to be able to treat patients as they transition from lower to higher levels of cognitive function.

In order to obtain the optimum balance between treatment needs and resource allocation, each treatment module will define particular criteria for hospital discharge within a one to three month window from randomization. Patients achieving these criteria may thus be discharged to home or community transition as early as one month after randomization. Similarly, all patients will be discharged to an appropriate transitional or domiciling program closer to their home no later than three months after randomization. The mean length of hospital stay needed to reach discharge criteria may differ among the four treatment groups, and thus becomes an additional secondary outcome measure impacting on cost.

General guidelines for the rehabilitation arms are as follows (see Table 1).

1. Total hours per week in all therapies should be no less than 15, and no more than 25 (Table 1). Treatment hours actually delivered per week will be recorded by subspecialty.
2. Patients randomized to the group A (Cognitive) arm should receive about five o ten hours of basic modalities such as OT, PT, speech, minimal diversionary activities, etc., and the remainder of the time in specific cognitive interventions.
3. Patients in the functional arm should receive five to ten hours of basic modalities as well, with the remainder of time being filled in with functional activities, widely viewed as therapeutic, but which are not specific in any way to cognitive rehabilitation (e.g., recreation therapy, music therapy, etc.). These will be supervised by a recreation therapist who will provide behavioral correction and guidance in an otherwise relatively unstructured setting, with an emphasis on practical functional performance.
4. It should be strongly encouraged that therapists who are not specifically assigned to administer cognitive interventions should minimize the use of cognitive therapies, and specifically, should spend no more that about 10 - 20% of their session times using these kinds of approaches. This would limit the total amount of cognitive interventions in group B (Functional) to about two hours a week. Furthermore, these would be less specific and intensive. For example, patients in group B might be trained in the use of a memory book, but group A (Cognitive) would be given intensive practice in effectively utilizing this compensatory technique; or group B patients would receive redirection when they became inattentive, while group A (Cognitive) would have specific attention training modules. Likewise, speech therapy in group B will be focused specifically on aphasia treatment in aphasic patients and motor functioning, swallowing, or mouth/tongue control in dysarthric or dysphagic patients. Lists of acceptable therapies for the two rehabilitation treatment approaches will be distributed as part of standardization training for therapists.
5. In addition, all therapists in group B, and those in group A (Cognitive) who are not directly assigned to administer the specific cognitive interventions, will keep daily records of the amount and nature of all cognitive interventions they used for each patient. Sites will be monitored

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

throughout the project, and periodic retraining will be provided in order to prevent treatment drift.

TABLE 1

APPROXIMATE HOURS OF THERAPY PER WEEK

	OT/PT Coping	Speech Therapy	Cognitive Therapy	Recreation Therapy	Total
Functional	5 to 12	2 to 5	0 to 2	10 to 15	15 to 25
Cognitive	5 to 12	*	10 to 15	0	15 to 25

* (embedded in cognitive program)

Transitional Management (Post Discharge)

At the completion of the inhospital treatment period, all patients will undergo an initial outcome evaluation (see below). They will then be referred to institutional or community transitional programs near their home, depending on their level of function, with specific recommendations for continued rehabilitation as indicated. patients will return for follow-up evaluations at six, 12, and 24 months postrandomization. Recommended transitional activities for a given individual will be consistent with the program (Cognitive or SOC) to which he or she was initially randomized. A case manager at each principal site will be assigned to maintain telephonic contact with the patient at a minimum of two-week intervals, and coordinate care with the receiving veterans or military facility closest to the patient's home. Arrangements will be made for local physical follow-up. It is anticipated that at least three levels of care may be needed.

1. High level patients discharged to home may require little more than referral to a community support group and regular communication with a case manager.
2. Intermediate level patients may require more intensive outpatient or community reintegration programs centered either at a participating VAMC, or a private facility contracted through various funding mechanisms.
3. Patients who remain at a low functional level (Rancho < 6) after the inpatient program may require long-term inpatient care at a DVA, domiciling, or private facility close to their home.

While it will thus be impossible to standardize transitional management across centers as tightly as the inpatient program, an attempt will be made to minimize any variation by providing specific recommendations for management at the time of discharge and coordinating closely with the receiving facility. In addition, data will be collected specifying the type and intensity of interventions received after discharge. Transitional treatments will thus be monitored over each hospital to determine and limit any referral biases which may merge.

STUDY MEDICATIONS

Sertraline

Sertraline or sertraline placebo will be administered in a gradually increasing dosage beginning with 25 mg daily (one-half caplet) for four days, then 50 mg daily (one caplet) for four days, then 75 mg daily for one week (one and one-half caplets), then 100 mg daily (two caplets). Should potential sertraline side effects, such as gastrointestinal upset or diarrhea, occur and persist, drug may be reduced to the previous dosage step. Drug/placebo will then be continued at the highest tolerated dosage step. Sertraline or sertraline placebo will be continued for a total of six months from randomization.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Methylphenidate

Methylphenidate or methylphenidate placebo will be administered in a gradually increasing dosage beginning with 5 mg (one capsule), twice daily for one week, then 10 mg (two capsule), twice daily. Medication will be administered at approximately 8:00 a.m. and 12:00 noontime. Should potential methylphenidate side effects, such as nervousness and jitteriness occur, drug will be temporarily reduced to the previous dosage step. Drug/placebo will then be continued at the highest tolerated dosage step. Study medication or placebo will be maintained until ten days prior to hospital discharge, at which time dosage will be cut in half. Test article will be discontinued at approximately one week prior to discharge.

Additional Medications

It is expected that certain patients will require additional medication for behavioral or seizure control. Patients with posttraumatic epilepsy manifested by at least one documented epileptic seizure will receive seizure prophylaxis with carbamazepine or phenytoin for at least six months postinjury. However, based on evidence from a recent controlled study,[32] TBI patients without seizures will not be maintained on anticonvulsants beyond one moth after injury.

Depressed patients judged by the consulting psychiatrist to require pharmacotherapy will receive a nonserotonergic antidepressant, such as desipramine beginning with 25 mg daily, and adjusted as needed.

Similarly, agitated patients not controlled with nonpharmacologic measures may be treated with carbamazepine or low-dose benzodiazepines, such as lorazepan. Agitated patients presenting danger to themselves or others, and judged by the local principal investigator to require chemical restraint, may be treated with haloperidol at the lowest possible dosage. Haloperidol, benzodiazepine, and carbamazepine prescriptions will be reviewed by the local principal investigator or their designee every day, with a view to minimize such treatment.

Doses and dates of all additional medications will be recorded in the case record.

Adverse Drug Experiences

The study drugs are both approved and in wide use, and significant adverse effects are not expected. In addition, dosage will be gradually increased as above. Nevertheless, rare patients may experience an allergic reaction to the test article (drug or placebo). If, in the opinion of the local principal investigator, the patient develops a significant allergic reaction to the test article, it may be discontinued, and the study monitor notified within 24 hours. An adverse experience form will be completed by the principal investigator for each patient with a serious or unexpected adverse reaction. The investigator must state whether in his or her opinion the adverse experience was related to the test article, concurrent drug therapy, underlying disease, a combination of these factors, or unknown. Lesser suspected drug side effects may also be managed by the local principal investigator as outlined above under *"study medications"*, with dose reduction of the test article or other treatment, instead of discontinuation. Patients with adverse experience on whom test article was reduced or discontinued may continue in the rehabilitation portion of the protocol, and will be followed to determine the outcome.

Completed adverse experience forms will be mailed to the monitor. The forms will include date of onset, severity, duration, the relationship to the test article, whether it was discontinued, any treatment given, and the outcome.

OUTCOME MEASURES

Primary Efficacy Criteria

1. Percent gainfully employed or in school at 12 months postrandomnization.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

2. Percent returning to independent living at 12 months postrandomization.

Secondary Outcome Variables

1. Performance on functional measures, including elements of the FIM and DRS scales.
2. Cost of intervention.
   Mean length of stay to reach discharge criteria.
3. Performance on selected quality of life/psychosocial function measures at discharge, six 12, and 24 months.
4. Performance on selected neuropsychological, behavioral, and mood state measures at discharge, six, 12, and 24 months.
5. Change in computerized EEG pattern.
6. Change in neurochemical markers.

Follow-up evaluation will be conducted by specialists not involved in either treatment arm. The evaluators will be blinded to drug treatment, although it may not be possible to maintain a blind on rehabilitation treatment arm. Methods which will be used to obtain high follow-up rates include: training of nursing coordinators, interim telephone follow-up, and securing of back-up addresses of relatives and/or friends.

Evaluation Parameters to be Followed

Please see evaluation Data Entry Forms.

A. Evaluation Schedule: Baseline, hospital discharge, and six, 12, and 24 months postrandomization.

B. Patient Evaluations: Outcome Variables. (Please see Data Entry Forms)

1.	Rehabilitation Medicine Evaluation	(1 hour)
	a. FIM, Occupational Therapy	
2.	Neurologic History and Examinations	(1 hour)
3.	Neuropsychologic Evaluation	(3 hours)
4.	Psychiatric Evaluation	(2 hours)
5.	Psychosocial Community Adjustment Evaluation Family Questionnaire	(1 hour)
6.	Magnetic Resonance Imaging (baseline and 12 months)	(1 hour)
7.	Quantitative Electroencephalography	(1 hour)
8.	Laboratory: CBC, P-4, Coagulation Panel	
9.	Special Laboratory Blood (20 cc), for experimental markers of CNS injury	

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

C. Costing Issues

Two major elements will impact on the cost of the programs: (1) the length of hospital stay, and (2) the complexity and amount of therapies provided. Cost measurement can be based on either, but the second is ultimately more accurate. We will be able to compute costs by obtaining facility costs per occupied bed day for each of the centers, and applying an overall per diem rate. However, this will not provide cost comparisons of the two alternative programs being tested at a given hospital, and is susceptible to the number of individuals enrolled in the program.

A charge for services approach will yield more accurate data and is thus preferable, but it will require a record of the amount and types of therapies the patients receive. These can then be costed using CHAMPUS or VA charges by CPT-4 codes and therapist salaries.

The following cost data will be collected:

1. The types and length of therapies that patients actually receive, and who provides them (CPT-4) codes). Attendance sheets will be maintained to determine if patients are receiving therapies.
2. Information on other procedures, not part of the treatment program, provided to the patient while he/she is in the hospital (ICD-9 codes).
3. Information on outpatient visits the patient received before and after the treatment programs.

ANALYSIS OF DATA

This is an experimental trial utilizing a factorial design in order to test hypotheses about the effects of rehabilitation treatment approaches and drug upon patient outcome in a population of hospitalized TBI patients. The drug treatments will be double-blinded and placebo controlled. The population to be studied consists of moderate to severe head injured patients, 17-55 years of age admitted to participating DVA centers.

Data will be collected at each of the participating hospitals and case report forms reviewed and signed by the principal investigator at each site. The central office statistical staff will review forms fro completeness and data quality, and will edit forms for keypunching. Data will be double-entry key punched, and discrepancies resolved with the central office. Once entered into the database, further data monitoring and checks will be conducted. Sites will also be visited periodically for monitoring of data validity, drug accountability, and the consistency of treatment content over time.

A total of 364 patients will be randomized into the study over a period of two years. Interim analysis will be conducted when N is about 182. The study may be terminated at this point, either if there is very strong evidence of efficacy, no evidence of efficacy, no evidence of efficacy, or significant adverse reactions. The interim analysis will be conducted at .01 alpha level. We would thus reject the null hypothesis (no efficacy at interim analysis, only if we found strong evidence of increased of increased efficacy for one of the treatment arms. The study will continue if interim analysis shows a positive trend toward such difference, but the results do not warrant stopping the trial prematurely. An independent monitoring committee will review the results of the interim analysis, and make the recommendation to stop or continue the trial. Investigators will remain blind to its deliberations.

The full trial can detect 15% improvement in the primary outcome measure at alpha = .04, 80% power with a two-tailed test, taking into account the interim look. Assuming an untreated rate of unfavorable outcome of 50%, the study has an 80% chance of detecting a population change of 15% or larger; that is, a decline to 35% unfavorable outcome.

Statistical analyses will be conducted with SAS, SPSS for Windows, and other mainframe and PC statistical programs. First, comparability of the four treatment groups prior to treatment will be

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

assessed by comparing relevant demographic and prognostic variables (i.e., Rancho level, age, time to treatment, sex, associated injury, etc.).

Analysis will then be done to determine whether treatment effects vary by research hospital. Central staff and principal investigators will seek to decrease variation by hospital effects by careful and continuous review of the forms completed by the evaluators, by monitoring patient accession rates, and by training new personnel. Centralized training, utilizing inter-rater reliability tests, will be conducted periodically. The effect of treatment by hospital interaction upon the end points will then be assessed with the Mantel-Haenszel statistic. Analyses of variance will be used to test such interaction upon continuous variables. Such interactions will be taken into account in analysis if the F ration for interaction is significant at even the 0.10 level.[33]

Comparison of the efficacy of the experimental (cognitive) versus functional treatment will be conducted. Analysis of variance and logistic regression analysis will be conducted to determine the treatment effect of the rehabilitation approach in conjunction with drug therapy. A separate evaluation of the drug's efficacy and safety for these patients will also be done. It is expected that certain subgroups of patients (i.e., those with depression or agitation) will benefit more than others from setraline. Some variables and additional analyses will compare the effect of treatment for different patient profile groups (impairment in cognitive skills versus impairment in social interaction skills). Depending upon the level of measurement of the variables (nominal or interval) chi-square and analysis of variance will be used to compare patients in the different treatment groups. Finally, analyses will be conducted separately on two Rancho level strata (Rancho 5-6 and Rancho 7), and combined if the results are comparable.

Study Monitoring Committee

A study monitoring committee will be established with the specific task of evaluating results of the interim analysis and making recommendations on the continuation or termination of the study at that time. All investigators remain blind to the deliberations of the committee. The committee will consist of the study statistician along with two senior research physicians and one senior statistician not otherwise associated with the study.

APPENDICES

Appendix A: Individual, Cognitive Rehabilitation Program (developed by Minneapolis, Tampa, Richmond VAMC)

Appendix B: Functional Rehabilitation Program (developed by Palo Alto VAMC)

Appendix C: Modified Apathy Scale

Evaluation Will Include

1. Standardized Neurological History and Examination (see Data Entry Forms).
2. Standardized Psychiatric Assessment, including a modified Present State Examination, Hamilton Depression Rating Scale, PANSS, and the SMAST and CAGE alcohol abuse scales (see Data Entry Forms).
3. Comprehensive Neuropsychological testing.

   The battery will include both standard tests of cognition and several experimental tests designed to probe for the orbitofrontal and anterior temporal lesions expected in these patients (see Data Entry Forms).
4. Rehabilitation Medicine Battery (see Data Entry Forms).
5. Psychosocial Outcome Battery (see Data Entry Forms).

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

6. Computerized EEG.

Computerized EEG will be acquired from 40 scalp locations during a three-minute eyes open and a three-minute eyes closed condition. The EEG samples will be carefully edited to eliminate artifact and then subjected to a power spectral analysis. The absolute and relative power in the delta, theta, alpha, and beta bands will computed, as well as the coherence and phase values between pairs of electrodes. Coherence and phase abnormalities in particular are hypothesized to correlate with diffuse axonal injury, and have been shown in prior studies to be commonly and relatively specifically seen in TBI patients. One goal of this project is to validate those findings. all of the power spectral values will be evaluated by a Z transform with respect to an age-matched reference EEG data base of 564 normal individuals. The Z scores will provide a quantitative "*normalcy*" measure in which the greater the magnitude and number of deviant Z scores, the more severe the brain injury. Z scores for each EEG measure will thus serve as the EEG outcome scores. The EEG outcome scores will be rerecorded and analyzed during the six-month, one-year, and two-year follow-up visits.

7. Noncontrast magnetic resonance imaging (MRI) will be performed in standardized sections with T_1 and T_2 weighted and gradient recovery images. Conventional CT scanning is not expected to add sufficiently to the MRI data to justify performing it routinely on our patients.

8. Routine laboratory, including CBC, chemistry, and coagulation profiles. Special laboratory for markers of CNS injury and recovery.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP)
PROTOCOL II

TRAUMATIC BRAIN INJURY REHABILITATION:
A CONTROLLED, RANDOMIZED MULTICENTER STUDY OF TWO INTERDISCIPLINARY PROGRAMS WITH ADJUVANT PHARMACOTHERAPY
VOLUNTEER INFORMED CONSENT

You have been asked to participate in a research study conducted at _____ VAMC. This is part of a larger, National study of head injury rehabilitation being conducted at four VA medical centers. It is very important that you read and understand the following general principles which apply to all participants in our studies:

1. Your participation is entirely voluntary.
2. You may withdraw from participation in this study or any part of the study at any time. Refusal to participate will involve no penalty, and will not otherwise affect your treatment.
3. After you read the explanation below, please feel free to ask any questions that will allow you to clearly understand the nature of the study.

Nature of the Study

Head injury is the principal cause of death and disability among young adults in America today, yet only recently has there been an increasing interest in the rehabilitation needs of head injured patients. In particular, given the remarkable ability of the young adult brain to compensate for injury naturally, it is not clear to what extent participation in a formal rehabilitation program will help speed recovery, or what type and duration of rehabilitation is best for a particular patient. Recent studies have also suggested that the standard, FDA-approved medications sertraline (Zoloft) and methyphenidate (Ritalin), when combined with rehabilitation, may help improve recovery from head injury. We propose to include you in a research study to: (1) evaluate the efficacy of two alternative rehabilitation programs, and (2) evaluate the efficacy of Zoloft or Ritalin in enhancing recovery from your injury. This protocol is designed to benefit all participants.

If you agree to participate, you will receive specialized TBI diagnostic testing including: neurologic, neuropsychologic, psychiatric, and rehabilitation examinations, along with magnetic resonance brain scan (MRI), and electroencephalogram (EEG). You will also have about 30 cc (two tablespoons) of blood drawn for routine laboratory, and for special experimental tests that may help us monitor the extent of your injury and your recovery.

You will then be assigned by random selection (flip of a coin) to one of four groups (cognitive or functional therapy, each with either active medication or placebo). The choice of which approved medication (Ritalin or Zoloft) might be used for you will depend on the results of your testing. However, neither you nor your doctors or therapists will know whether you are on active medication or placebo until the end of the protocol. You will remain in the rehabilitation program for approximately two months (plus or minus one month), depending on how well you recover.

At that time you will be discharged to home or to the veterans facility closest to your home for follow-up care. patients in the Zoloft study group will be asked to continue taking their medication for a total of six months. During this time, you or your family will receive follow-up telephone calls from a case manager, to ensure that you are continuing to recover well. Six, 12, and 24 months from entry into study all patients will return to _____ VAMC for a several-day reevaluation. These evaluations may include questionnaires regarding your recovery, to be completed by you, your family, and/or by those friends or work supervisors whom you designate.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Duration of Participation

The study will last two years: approximately four to 12 weeks of initial treatment, and about 20 months of follow-up. You will hospitalized for the initial treatment period and then for a few days each at six, 12, and 24 month follow-up.

Foreseeable Risks or Discomforts

There are no significant foreseeable risks or discomforts from the rehabilitation therapy. However, patients will be expected to participate in good faith in the rehabilitation process.

The two medications to be used in the study have been shown to be safe and have been approved by the Food and Drug Administration (FDA) for general use in treatment of depressions, apathy, or attention disorders. Significant side effects of Zoloft are unusual, but may include temporary abdominal symptoms, dry mouth, temporary sexual function changes, and sleep changes. Side effects of Ritalin may include temporary nervousness or insomnia.

Potential Benefits

While we must recognize that a brain injury such as you have suffered may result in long-term impairments, you are being offered participation in this program because we expect you to benefit from it. This study has been designed to benefit all participants, regardless of the group to which they are randomized. The goal is to smooth your return to independent living and work. The extensive diagnostic battery, treatment, and follow-up, which all study participants will receive exceeds the current standard of care for this type of head injury.

Confidentiality

Research records of your participation in this study will be maintained by the principal investigator. These records may be reviewed by the hospital Human Use Committee/Institutional Review Board as part of their responsibilities for insuring the protection of research volunteers. However, confidentiality will be strictly maintained. You will not be identified by name in any publication or presentation resulting from this study.

Circumstances Under Which Participation May Be Terminated Without Your Consent

Your participation may be terminated without your consent if health or other conditions occur that might be dangerous or detrimental to you or your health, or if the principal investigator determines that it would be in your and other participants best interest.

Safeguards

There are no known health risks associated with participation in the study.

Approximate Number of Subjects in Study

There will be a total of 364 patients in the study, or about 90 patients at each of the four participating centers.

Alternative Procedures or Treatments

If you choose not to participate in the study, you will receive the standard rehabilitation for moderate to severe head injury as available at this facility or at the proper VA medical facility closest to your home. Your failure to participate will not otherwise prejudice your treatment.

Additional Costs that May Result from Participation

No significant additional costs to you for participation in this study are expected.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Significant New Findings

Any significant new finding s that develop during the study which could affect your willingness to continue participation will be made available to you the results of the research will be made available to you, if you so desire.

Investigational Drug

This study does not involve the use of any experimental drugs.

Waiver of Compensation for Private Citizens

Participation in this study will not affect any benefits to which you might be otherwise entitled as a military or VA beneficiary. However, you agree that you will not be entitled to any additional compensation for your participation in the study, and you waive any future claim against the US government for such compensation.

Signatures

I have been given the opportunity to discuss pertinent aspects of the research study and to ask questions, and I hereby consent to participation in the project as described in this consent form.

_____ _____

Volunteer or Guardian Date

_____ _____

Witness Date

_____ _____

Counseling Physician Date

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX A

ATTENTION PROCESS TREATMENT MODULE

ASSUMPTIONS OF THE MODULE

The present treatment model reflects a cognitive approach to treatment that is restorative in nature. Its goal is to improve functional activity by improving or restoring cognitive processes that support those activities. The tasks themselves may not be functional in nature, but are intended to result in improvement in functional activity. It involves a variety of treatment tasks that target a specific cognitive process, in this case attention. The treatment goals and tasks are hierarchically organized, moving from simpler goals and tasks to more complex ones. Treatment tasks are repeated until a specified level of mastery is attained. Repeated stimulation involving therapeutic tasks is thought to facilitate reorganization of the targeted cognitive process.

RATIONAL AND THEORECTICAL BASIS FOR THE MODULE

The proposed model for treatment of attention in patients with TBI is based on Sohlberg and Mateer's (1986) Attention Process Training (APT). The treatment program is a "*process specific*" therapy that is restorative in nature, in that it is designed to improve attentional function itself rather than to compensate for attentional impairment. Attention is thought to be the foundation of other cognitive processes, such as memory and reasoning. Therefore, treatment of attention may indirectly improve the function of a number of a number of other cognitive processes.

Implicit in the theoretical foundation of the program is that attention is strongly associated with the concept of working memory, a system for temporary storage and manipulation of information in complex cognitive tasks. It is comprised of a capacity-limited central executive and two subsidiary slave systems: (1) the articulatory loop (for storage and maintenance of speech-based information), and (2) the visuospatial sketch pad (for storage and maintenance of visuospatial images). The central executive is described as a controller of memory that allows for temporary storage of information within the slave systems while attention is shifted to other information and processing. It is also assumed to retrieve information from long-term memory that is relevant to ongoing processing.

From a clinical standpoint, the treatment program addresses four separate levels of attention. Sohlberg and Mateer describe them as follows:

1. Sustained Attention: The ability to maintain a consistent behavioral response during continuous, repetitive activity.
2. Selective Attention: The ability to maintain a cognitive set which requires activation and inhibition of responses dependent upon discrimination of stimuli. This includes the ability to screen out extraneous visual or auditory information.
3. Alternating Attention: The capacity for mental flexibility which allows for moving between tasks having different cognitive requirements.
4. Divided Attention: The ability to simultaneously respond to multiple tasks.

DESCRIPTION OF THE MODULE

The module itself is comprised of a large number of different tasks. Each task is intended to target one of Sohlberg and mateer's four levels of attention. The treatment program is divided into three levels of difficulty: (1) low-level tasks focus primarily on sustained attention using simple vigilance tasks and self-generated tasks that are fairly automatic in nature; (2) intermediate and high level tasks focus on selective, alternating, and divided attention, as well as sustained attention tasks requiring a higher degree of mental control; (3) treatment tasks include vigilance tasks in which the patient is asked to sustain a particular activity over a period of time. There are audiotaped vigilance tasks that require the patient to listen to a series of stimuli and perform mental operations to identify appropriate targets. These tasks range from simple vigilance (patient listens to a series of numbers and responds

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

to the number "2"), to complex tasks requiring a high degree of mental tracking (e.g., patient listens to a series of numbers and responds if a number is one less than three times the previous number). All of these tapes can be presented with competing background noise (a radio newscast) to force selective attention. There are also vigilance tasks that involve the visual modality. These include computerized attention tasks, as well as a series of concellation tasks of increasing complexity. Cancellation tasks can be presented with distractor overlays to force selective attention. The program includes several tasks that alternating attention using Stroop-like tasks, as well as a number of self-generated attentional activities (e.g., serial subtraction) that require the patient to initiate and maintain a consisten attentional set over a period of time. Moderately and severly impaired subjects will receive daily one-hour treatment sessions. Mildly involved subjects will receive daily half-hour treatment sessions. Attentional capacity will be measured using versions of the Continuous Performance Test and the Paced Auditory Serial Addition Test, as well as a questionnaire developed for this purpose.

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX A

PRAGMATICS TREATMENT MODULE

ASSUMPTIONS OF THE MODULE

The proposed treatment module reflects a cognitive approach that is restorative in nature. The goal is to improve functional communication by improving or restoring pragmatic skills essential to social communication, which are frequently disrupted by traumatic brain injury. This module assumes that specific pragmatic deficits can be identified and remediated by specific treatment.

RATIONALE AND THEORETICAL BASIS FOR THE MODULE

Pragmatics refers to a system of behavioral rules that clarify or modify the meaning and use of language in a given situational or social context. It focuses on abilities which relate to the use of language in managing conversational exchanges between two or more people. Research has shown that individuals lacking pragmatic skills showed decreased success in school or the work place.

Historically, disruptions in language have been referred to as aphasia. However, classic aphasic characteristics of reduced capacity to interpret and formulate language symbols have been shown to have low incidence in the traumatically brain injured (TBI) population. While the TBI patient retains the constructs of language, the ability to use language effectively in interpersonal situations has been shown to be the most pervasive communication impairment documented in the TBI population. This is commonly referred to as a deficit in pragmatics.

Pragmatic disturbances following TBI include: expressive disturbances in disorganization of the message, impaired message selections and modification, incomplete messages, absence of detail or excessive information. Nonverbal features of communication may be impaired in the inappropriate use of facial expressions, gestures, proxemics, and eye contact. Additionally, impaired use of conversational rules in the use of acknowledgments, referencing and presupposing, turn taking, and topic selection are prevalent.

In order for an individual to demonstrate and appropriately use pragmatic techniques, there must be firmly established/reestablished basic cognitive and language skills. Thus, individuals at a Rancho level 5 or above will be considered appropriate for this module.

DESCRIPTION OF THE MODULE

After a comprehensive review of the literature, two resources were identified and modified for the pragmatics module. For higher functioning individuals, Sohlberg, et al., 1992, *Improving Pragmatic Skills in Persons with Head Injury* was selected as an appropriate guide. For lower functioning individuals, *Building Functional Social Skills: Group Activities for Adults* (Dikengil and Kaye, 1992) was selected.

Following identification of specific deficits, individuals will participate in activities designed to facilitate pragmatics in one of five skill areas: initiation, topic management, turn taking, verbal organization, or active listening. Each skill will be taught in one of these formats depending on the assessed level of awareness of the individual. For individuals who are just beginning to be aware of and recognize their deficits (Intellectual Awareness), module tasks will be rather simple and concrete; while for those who are more advanced and at higher level of awareness (Anticipatory Awareness), tasks will be more complex and abstract. For example, an individual with identified deficits in turn taking during conversation at the level of intellectual awareness would be cued whenever interrupted during conversation, while an individual at the level of anticipatory awareness would be required to practice these skills without cueing in unfamiliar environments. Tasks provided at the intellectual awareness level, emergent awareness level, and anticipatory awareness level, are roughly equivalent to instructional, practice, and generalization phases of task acquisition.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Treatment will take place for three one-hour individual sessions and two one-hour group sessions per week. Videotaping will be utilized as a medium for self and guided feedback and analysis. Target goals will be identified for carry over and monitoring by intradiscipline staff in the context of other therapies and unit based activities throughout an individual's day.

Consistent with reported studies in the area of pragmatic, Speech-Language pathologists have been designated as the primary treatment facilitators.

Three assessment procedures have been identified:

1. Analysis of videotaped conversation in an unstructured free conversation observation.
2. Analysis of structured narrative.
3. Analysis of a referential communication task.

Interrater reliability will be established for analysis of pragmatic skills.

Pre and post-test measures of performance will be assessed utilizing the RIC Evaluation of Communication Problems in Right Hemisphere Dysfunction (RICE-R).

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX A

PROSPECTIVE MEMORY TRAINING MODULE

Prospective Memory refers to the ability to remember to carry out intended actions at a specified future point in time.

ASSUMPTIONS OF THE MODULE

The treatment model selected addresses the areas of restoration of a deficient cognitive function, as well as compensation training to manage residual deficiencies in cognitive functioning; in this case, prospective memory. As opposed to traditional clinical models of memory retraining, prospective memory process training attempts to retrain skills in a more naturalistic, ecologically valid contest. Through the use of hierarchically organized tasks directed at the remediation of the underlying prospective memory process, the ultimate goal of the program is to extend systematically the amount of time an individual is able to remember to carry out specified tasks. The second portion of the program, compensation training, results from the frequency and persistence of residual memory deficits, which often limit successful outcomes. Through systematic, formal training procedures, individuals learn to use an external aid to minimize the barriers to independent living. As both retraining and compensation address the underlying cognitive process in more real-life tasks, improvements in prospective memory will result in a generalized improvement in functions across behaviors and situations.

RATIONALE AND THEORETICAL BASIS FOR THE MODULE

The programs selected for the treatment of prospective memory deficit are prospective memory process training and memory notebook training, both the work of M. M. Sohlberg and C. A. Mateer (1985, 1986, 1989). Traditional models of memory usually viewed it as a purely dichotomous storage system, with only short-term or long-term components. Subsequent models conceptualized memory according to levels of processing with components of attention/encoding, and storage/retrieval. In attempts to better document the functional capacity of prospective memory, Sohlberg, Mateer, and Crinean (1986) conducted a survey in which both head injured and control subjects reported that the most frequent kind of memory failure they experienced was that related to encoding information and then retrieving it at a future point in time; that is, attention and prospective memory. Prospective memory process training attempts to improve the cognitive process of encoding and retrieval of information, whereas compensatory memory book training provides the skill required to actively and systematically encode and retrieve information through the use of external aids.

DESCRIPTION OF THE MODULE

Prospective memory process training will be carried out in a dual-treatment paradigm. It will address both the ability to recall the task to be carried out, as well as the ability to carry it out at a designated future point in time. Patients will be asked to remember a task to be performed and a time in the future at which to perform it while engaging in another cognitive activity. They will use timed cues such as watching a clock or watch in this training. Time is usually extended by two to five minute intervals as individuals meet program criteria.

Compensatory memory book training will include three phases.

In the acquisition phase, individuals will be asked a series of questions about the sections and use of the sections in the memory notebook.

Prospective Memory Training Module

In the application phase, individuals will apply what was learned in the previous phase and use it in treatment through role-play of situations.

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

In the adaptation phase, functional training will occur in real-life situations.

The module will be carried out by levels of severity in individual (1:1) treatment sessions.

Low Level: Thirty to 45-minute individual treatment sessions for prospective memory training and memory notebook training at the acquisition phase. Prospective memory training will also be embedded in other treatment modules at this level. A 30-minute orientation group is included at this level.

Intermediate Level: Thirty to 45-minute individual treatment sessions for prospective memory tasks of increased complexity (longer time intervals) and application phase of memory book training. Orientation group optional.

High Level: Thirty to 45-minute individual treatment sessions with continued increased complexity of prospective memory tasks (longer time intervals, dual tasks assigned), and adaptation phase of memory book training. Prospective memory tasks will be assigned during treatment sessions, as well as throughout the day.

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX A

EXECUTIVE FUNCTIONS TREATMENT MODULE

A definition for executive functions is not universally agreed upon. However, for the purposes of this program, we will utilize Muriel Lezak's description: *"The executive functions can be conceptualized as having four components: (1) goal formulation, (2) planning, (3) carrying out goal-directed plans, and (4) effective performance"* (Lezak, 1983).

ASSUMPTIONS OF THE MODULE

The treatment model for the remediation of executive functioning deficit requires the ability to perform functional, everyday tasks which assume a degree of prior mastery of the underlying cognitive processes of attention and memory (and memory compensation). Other areas not directly addressed in the cognitive arm, but which need to be functional to some extent, include visual processing and motor planning. Unlike other cognitive process areas (discussed elsewhere) which rely heavily on performing specific tasks and degree of accuracy of such performance, executive function refers to the areas of thinking involved in performing the task; more specifically, HOW the task was accomplished. Executive functions training relies on systematic, guided practice of the *"how to's"* of functional independent problem solving.

RATIONALE AND THEORETICAL BASIS FOR THE MODULE

To our knowledge, there are no definitive or widely-used tools for the assessment or treatment of executive functions. We do know that many therapy and daily-life situations during the course of a hospital stay reveal deficits in planning, organizing, initiating, self-monitoring, and self-correction. The proposed treatment model incorporates portions of executive functions: model and management, a supplement to the process-specific approach to the cognitive rehabilitation work of Sohlberg and Mateer (1989), and portions of Mark Ylvisaker's, *A Program for Training the Executive System* (1988). Theoretical attraction to this program stems from the fact that it provides the framework needed to directly address a deficit that is frequently observed by clinicians who work with these individuals. The deficit has been widely documented as stemming from damage to the frontal and prefrontal cortex.

DESCRIPTION OF THE MODULE

The executive functions training program will be carried out in three treatment areas:

1. Skill training through teaching of task-specific routines. This assumes that the patient is not capable of carrying out a wide variety of routines, such as those of activities of daily living, due to context dependency, perseveration, limited insight and awareness, and severe cognitive disorders of attention and memory.

2. Direct restitutive retraining of the executive control system. This includes formal training through daily routines and/or paper/pencil tasks of the following components: (a) goal setting, (b) planning and organizing, (c) initiation, (d) error detection and correction, and (e) self-monitoring and self-evaluation.

3. Metacognitive training and awareness. This includes education on frontal lobe injury and deficits. Includes, as well, continued direct retraining of the executive control system, as in number two above. The module will be carried out by levels of severity during both individual (1:1) and group treatment sessions.

Low Level: Indirect executive functions treatment through daily routines. Staff to use lists of things to do, steps required to accomplish a task, pointing out errors, and modeling of correct responses.

Intermediate Level: Individual 30-minute sessions utilizing paper/pencil tasks as a means to create situations for utilizing the executive system. Degree of complexity of task changes minimally,

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

however, degree/amount of external cueing required to complete the task (maximum, moderate, minimal) will dictate advancement in the program.

High Level: Individual and group treatment sessions, 60 minutes each, utilizing education pamphlets and videos to increase awareness and develop conscious ability to self-instruct and self-monitor.

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FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX B

FUNCTIONAL REHABILITATION PROGRAM

The functional program for the DVHIP project will be designed to test the hypothesis that intensive rehabilitation given with a functional focus, as compared to one with a cognitive focus, is effective in providing a beneficial effect on the head injury victim's recovery. Unlike the cognitive arm of the protocol, there will be no specific "cognitive strategies" used in this arm. Instead, rehabilitation will be directed toward maximal functional recovery using individual and group therapies which are goal-oriented toward independent living skills.

Medical rehabilitation physicians and nurses will oversee all patients in both the functional and cognitive arms.

TYPES OF TREATMENTS

Listed below are specific interventions and treatments that will be included or specifically excluded from the Functional program:

*NOTE: Bolded, underlined areas are parts of the program that are emphasized and included in this program, and are minimally emphasized or absent in the Cognitive program.

Range of Motion (PT, OT, KT, RT)

ADL's (OT)

Assistive Devices (OT, PT, KT)

Progressive Resistive Exercises and Other Exercises (PT, KT, OT, RT)

Coordination and Balance Training (PT, KT)

Endurance Training (PT, KT, OT)

Flexibility (PT, KT, OT)

Neglect and Visual-Perceptual Training, particularly as related to ADL's, Mobility (OT, PT, KT)

Swallowing (SP)

Motor Speech (SP)

Vocal Pathology (SP)

Mobility Training (PT, KT, OT, RT)

Gait Training (PT, KT)

Memory Book (OT, SP, PT, KT, RT)

Checklists/Schedules, as related to Daily Activities and Planning (OT, SP)

Posture Training (PT, KT)

Performance and Task-Oriented Activities (PT, OT, KT, SP, RT)

Prevocational Activities (OT)

Orthotic Device/Prosthetic Device Fitting (OT, PT, KT)

Kitchen Skills and Mobility (OT, RT)

Transfer Training (PT, OT, KT, RT)

Fitness Programs (RT)

Sports (RT)

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

Language Dysfunction (aphasia, alexia, agraphia) (SP)

Community Mobility (including shopping, using the bus, making change, etc.) (OT, RT)

Problem Solving Skills, as related to Functional Activities (SP, OT, PT, RT)

Behavioral Management, Coping Skills (Psychiatry)

Counseling and Patient/Family Education (Psychiatry, SW, all)

Socialization and Interpersonal Skills (RT)

Driver Training/Adaptive Equipment for Driving (KT)

Excluded From Functional Group, But Included in Cognitive Arm

Awareness/Attention Training

Interpersonal Aspects of Speech (turn taking, initiation, verbal organization, active listening, topic management)

Formal Training and Practice with Memory Book

Memory and Executive Function Homework

Underlying Process Training

Attention Process Training

Prospective Memory Process Training

Executive Function Training

Pragmatic Speech Training

1. Use of the memory notebook for this group will be limited to the use of a personal log/calendar and timetable. All therapists/nurses combined may not use the memory notebook training more than 30 minutes total a day.
2. Videotaping may be used for gait evaluation and training and socialization skills training. Periodic videotaping of therapy sessions will be utilized to assure consistency of the protocol among the participating sites.
3. Goals will be functionally oriented, as team-specific goals are a JCAHO requirement and cannot be excluded from either group.
4. Since Recreation therapy will be spending 10 to 15 hours per week with these patients, their activities will be defined across the various treatment centers. These activities may include: board games, sports, hobbies, cooking groups, community outings, group and individual exercise programs. Workbook activities and cognitive computer programs will be excluded.
5. Infrequent activities (once a month or less) is acceptable to both groups. One example is pet therapy, which recreation therapy conducts at the Palo Alto VAMC about once a month, or every other month.

PERSONNEL

Full-Time Employee:

0.5 Occupational Therapist

0.5 Physical Therapist

0.5 Speech Pathologist

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

SAMPLE SCHEDULE

FUNCTIONAL PROGRAM PATIENT

	MON	TUES	WED	THURS	FRI
8:00 a.m.	OT (ADL)	OT (ADL)	OT (ADL)	OT (ADL)	OT (ADL)
9:00 a.m.	Speech	Speech	Speech	Speech	Speech
10:00 a.m.	----------	----------	Rest	----------	----------
11:00 a.m.	----------	Group/Individual Exercise Program			----------
12:00 a.m.	----------	----------	Lunch	----------	----------
1:00 p.m.	PT/KT	PT/KT	PT/KT	PT/KT	PT/KT
2:00 p.m.	OT	Mobility	Therapy	OT	Cooking
3:00 p.m.		Group	Outing		Group
4:00 p.m.					
5:00 p.m.					

FIGURE 23-4-5 DEFENSE AND VETERANS HEAD INJURY PROGRAM (DVHIP) - PROTOCOL II (CONTINUED)

APPENDIX C

MODIFIED APATHY SCALE

Code:	Not at all 1	Slightly 2	Somewhat 3	A lot 4

1. Are you concerned about your condition? _____
2. Do you put much effort into things? _____
3. Do you spend your free time doing things that interest you? _____
4. Getting things done during the day is important to you (e.g., getting to appointments, receiving medical care)? _____
5. When something good happens, you are pleased or excited? _____
6. Do you have motivation, or a desire to do things? _____

Total Score: _____

FIGURE 23-4-6 SAMPLE OF DEERS ELIGIBILITY VERIFICATION LETTER TO BE ISSUED TO THE VAMC PARTICIPATING FACILITY

VAMC Participating Facility
Street Address
City, ST 00000

Dear _____:

This is to inform you that the following patient is eligible for TRICARE benefits and may be considered for participation into the DVHIP Protocol II.

Name of Patient: _____

Sponsor's Social Security Number: _____

If you have any questions or concerns, you may contact me at the address in the letterhead or call 1-800-XXX-XXXX.

Sincerely,

Title